

Start	Duration	
7 June 2011 –Meeting level, Renaissance Hotel		
17:30	Until 19:30	Registration <i>(Foyer, level E-2)</i>
8 June 2011 –Meeting level, Renaissance Hotel		
7:00	Until 19:30	Registration and Information <i>(Foyer, level E-2)</i>
8:30		Introduction and Welcoming Remarks <i>(Américas, level E-2)</i>
	15 minutes	Workshop Co-Chairs Mr. Lahouari Belgharbi, WHO Dr. Endang Woro, DCVRN Dr. Daniel Miller, HHS
	10 minutes	Brazilian National Health Surveillance Agency (ANVISA) Dr. Dirceu Brás Aparecido Barbano, ANVISA, Brazil
	10 minutes	Brazilian Ministry of Health Dr. Zich Moysés, Brazilian Ministry of Health
	10 minutes	U.S. Department of Health and Human Services Dr. Bruce Gellin, HHS
9:15		Setting the Stage <i>Moderator: Dr. Daniel Miller, HHS</i> <i>(Américas, level E-2)</i>
	10 minutes	Overview of Vaccine Capacity Building Stakeholders' Workshop Series & path forward for GAP-2 Dr. Daniel Miller, HHS
	10 minutes	Readout from International Vaccine Technology Workshop, 17-18 September, Hyderabad, India Dr. Daniel Miller, HHS
	15 minutes	Readout from the First WHO NRA strategic forum of regulatory agencies for vaccines, 3-5 May 2011, Bangkok, Thailand Mr. Lahouari Belgharbi, WHO
	10 minutes	Workshop goals and desired outcomes Mr. Lahouari Belgharbi, WHO
	30 minutes	Q&A and Discussion
10:30	30 minutes	Morning Break <i>(Foyer, level E-2)</i>
11:00		Keynote Addresses <i>Moderator: Mr. Lahouari Belgharbi, WHO</i> Challenges of Enhancing Vaccine Regulatory Capacity in Developing Countries: Stakeholders' Perspectives <i>(Américas, level E-2)</i>
	15 minutes	WHO Perspective Mr. Lahouari Belgharbi, WHO
	15 minutes	Perspectives of Policy Makers Dr. Zich Moysés, Brazilian Ministry of Health
	15 minutes	Perspectives of Technical Partners Dr. Elwyn Griffiths, Health Canada
	30 minutes	Q&A and Discussion
12:15	75 minutes	Lunch <i>(Amazônia, level E-3)</i>

Start	Duration	8 June 2011 –Meeting level, Renaissance Hotel				
13:00	15 minutes	Session 3	<i>Moderator: Mr. Lahouari Belgharbi, WHO</i>			<p style="text-align: center;">The Role of WHO in Influenza Vaccine Oversight <i>(Américas, level E-2)</i></p> <p>WHO guidance on what constitutes a functional national regulatory authority (NRA) and national control laboratory (NCL) Mr. Lahouari Belgharbi, WHO</p> <p>WHO strategy to facilitate regulatory decision making for licensing, marketing authorization and deployment of 2009 Pandemic Influenza vaccines world-wide Dr. Claudia Alfonso, WHO</p> <p>WHO prequalification process Dr. Laszlo Palkonyay, WHO</p> <p>Q&A and Discussion</p>
	15 minutes					
	15 minutes					
	30 minutes					
14:50	30 minutes	Afternoon Break <i>(Foyer, level E-2)</i>				
15:20	15 minutes	Session 4	<i>Moderator: Dr. Christoph Steffen, Agence de Medecine Preventive, SIVAC Initiative</i>			<p style="text-align: center;">Interactions between NRAs and Decision/Policy Making Government Bodies in Influenza Vaccine Preparedness <i>(Américas, level E-2)</i></p> <p>Importance of the collaboration between National Regulatory Authorities (NRAs) and National Immunization Technical Advisory Groups (NITAGs) to ensure that vaccines are delivered adequately to the population Dr. Christoph Steffen, Agence de Medecine Preventive, SIVAC Initiative</p> <p>PANEL DISCUSSION: Introduction of New Vaccines in Lower Income Countries without production capacity: decision making and respective roles of the Food and Drugs Board and the Ministry of Health and the EPI Manager Mrs. Delese Mimi Darko, Food and Drugs Board, Ghana Dr. K.O. Antwi-Agyei, Ghana Health Service Mr. Samuel Boateng, Ministry of Health, Ghana</p> <p>PANEL DISCUSSION: Introduction of New Vaccines in Lower Income Countries with national production capacity: decision making and respective roles of the NIHE, Ministry of Health and the Regulatory authority Dr. Nguyen Minh Hang, Ministry of Health, Viet Nam Ms. Nguyen Hong Nhung, Drug Administration of Viet Nam Dr. Nguyen Van Cuong, National Institute of Hygiene and Epidemiology, Viet Nam</p> <p>Q&A and Discussion</p>
	30 minutes					
	30 minutes					
	15 minutes					
16:50	10 minutes	Summary and Wrap Up of Day 1 <i>(Américas, level E-2)</i>				
18:30	120 minutes	Session 5	Working Dinner - Regional Breakout Sessions <i>(Buffet in Foyer, levels E-2 & E-3)</i>			<p>Topics for discussion* :</p> <ul style="list-style-type: none"> • Communications between NRAs in the Region • Regulatory capacity in the Region • Establishment of coordinating and networking regional regulatory authorities
			<p>African & Eastern Mediterranean Region <i>(Pantanal, level E-3)</i> <i>Moderator: Ms. Esnat Mwape, Pharmaceutical Regulatory Authority, Zambia</i></p>	<p>South East Asia Region <i>(Andes, level E-2)</i> <i>Moderator: Dr. Dede Kusmiaty, National Agency of Drug and Food Control, Indonesia</i></p>	<p>Americas Region <i>(América do Sul, level E-2)</i> <i>Moderator: Mr. Mario Matos Marcelo Moreira, ANVISA, Brazil</i></p>	

Start	Duration	9 June 2011 –Meeting level, Renaissance Hotel	
7:00	Until 17:00	Registration and Information (Foyer, level E-2)	
8:30		<i>Moderators: Dr. Enver Yousuf, Medsafe, New Zealand & Dr. Jeewon Joung, FDA, Korea</i> The Regulatory Pathway and Unique Challenges for Influenza Vaccines (Américas, level E-2)	
	15 minutes	Session 6	Assortment of vaccine technologies (e.g. killed virus, live attenuated, recombinant subunit, viral vector, VLP, egg-based, cell-based, adjuvanted) Dr. Laszlo Palkonyay, WHO
	15 minutes		An overview of Seasonal and Pandemic Influenza Vaccine Production (including manufacturing processes) Dr. Michael Pfeleiderer, EMA
	15 minutes		An overview of clinical requirements and non-clinical considerations for influenza vaccines Dr. Norman Baylor, US FDA
	15 minutes		Safety monitoring throughout the influenza vaccination cycle, including post-marketing surveillance Dr. Robert Ball, US FDA
	30 minutes		Q&A and Discussion
10:00	30 minutes	Morning Break (Foyer, level E-2)	
10:30		<i>Moderator: Othmar Engelhardt, NIBSC, UK</i> Global Preparedness for Influenza Vaccines (Américas, level E-2)	
	20 minutes	Session 7	The WHO Global Influenza Surveillance Network (GISN) Dr. Varja Grabovac, WHO
	45 minutes		Perspectives from Essential Regulatory Laboratories Dr. Shigeyuki Itamura, National Institute of Infectious Diseases, Japan Dr. Othmar Engelhardt, NIBSC, U.K. Dr. William McCormick, US FDA
	35 minutes		Q&A and Discussion
12:10	80 minutes	Lunch (Amazônia, level E-3)	
13:30	150 Minutes	Breakout Sessions	
		Session 8A	Session 8B
		Session 8A: Open only to participants from NRAs <i>Moderators: Elwyn Griffiths, Health Canada & Mr. Mario Matos Marcelo Moreira ANVISA, Brazil</i> (América do Sul, level E-2) Panel Participants: Dr. Ding Lixia, SFDA, China Mrs. Olga Lidia Jacobo, CECMED, Cuba Dr. Jeewon Joung, FDA, Korea Dr. Aaron Sosola, Pharmacy, Medicines & Poisons Board, Malawi Dr. Enver Yousef, Medsafe, New Zealand Dr. Tasanee Lorchaivej, Thailand Food and Drug Administration Topics for Discussion* : <ul style="list-style-type: none"> • Communications between in country-NRAs and policy makers • Challenges faced by NRAs and policy makers in responding to the H1N1 2009 influenza pandemic • Establishment of coordinating and networking between NRAs and policy makers at regional level 	Session 8B: Open to all participants except NRA representatives <i>Moderators: Daniel Miller, HHS & Dr. Roman Prymula, Ministry of Health of the Czech Republic</i> (América do Norte, level E-2) Panel Participants: Dr. Sandra Marie Deotti, Ministry of Health, Brazil Mr. Samuel Boateng, Ministry of Health, Ghana Dr. Masato Mugitani, Ministry of Health, Japan Dr. Phan Trong Lan, Ministry of Health, Viet Nam Topics for Discussion* : <ul style="list-style-type: none"> • Communication and information sharing • Country's experiences with WHO vaccine deployment during the 2009 H1N1 pandemic (donors and recipients) • Establishment of coordinating and networking regulatory authorities and policy making authorities

Start	Duration	10 June 2011 –Meeting level, Renaissance Hotel	
7:00	Until 17:00	Registration and Information (Foyer, level E-2)	
8:30		<i>Moderator: Dr. Maria Luz Pombo, PAHO</i>	
		Inventory of Regulatory Models (Américas, level E-2)	
	25 minutes	Session 9	European Medicines Agency (EMA): a model for the coordination of networking National Agencies Dr. Marie-Hélène Pinheiro, EMA
	15 minutes		Capacity building models to address needs/gaps
	10 minutes		Overview of WHO Department of Immunization, Vaccines and Biologicals & How the WHO and its regional offices support Regulatory Capacity Building in developing countries Mr. Lahouari Belgharbi, WHO
	60 minutes		Case Study: PAHO support to Regulatory activities in Latin American and Caribbean countries • Brief introduction to PAHO assessment tool Dr. Maria Luz Pombo, PAHO
	30 minutes		• Roundtable discussion Representative from Regulatory Agency approved as functional by WHO/PAHO ○ Mrs. Laura Castanheira, ANVISA, Brazil PANDRH Vaccines Working Group Coordinator ○ Dr. Olga Lidia Jacobo, CECMED, Cuba Coordinator of the Regional Network of Quality Control of Vaccines Laboratories (RRLNCCV) ○ Dr. Ana Agaton, INHRR, Venezuela Representative of a Regulatory Agency of Regional Reference in process of being approved as functional by WHO/PAHO ○ Dr. Marina Rossi, ANMAT, Argentina
		Q&A and Discussion	
10:50	30 minutes	Morning Break (Foyer, level E-2)	
11:20		<i>Moderator: Dr. Liliana Chocarro, LC Plus Consulting</i>	
		WHO-Supported Regulatory Capacity Building Networks in Vaccine Trials in Developing Countries (Américas, level E-2)	
	10 minutes	Session 10	Overview of WHO-supported regulatory capacity building networks Dr. Liliana Chocarro, LC Plus Consulting
	15 minutes		DCVRN Dr. Endang Woro, DCVRN
	15 minutes		AVAREF Dr. Aaron Glyn Sosola, Pharmacy, Medicines & Poisons Board, Malawi
	15 minutes		Q&A and Discussion
12:20	60 minutes	Lunch (Amazônia, level E-3)	
13:20		<i>Moderator: Ms. Cathy Parker, Health Canada</i>	
		Case Studies: Mentoring Partnerships Between Regulators (Américas, level E-2)	
	15 minutes	Session 11	Health Canada and the Central Drugs Standard Control Organization of India Ms. Cathy Parker, Health Canada
	15 minutes		Thai FDA/Australian TGA Formal training Dr. Yupin Lawanprasert, Thai FDA
	20 minutes		South-South Cooperation: Mentoring model Mrs. Laura Castanheira, ANVISA, Brazil and Mrs. Olga Lidia Jacobo, CECMED, Cuba
	25 minutes		Q&A and Discussion

Start	Duration		
10 June 2011 –Meeting level, Renaissance Hotel			
14:35	15 minutes	Session 12	Outcomes from Breakout Sessions <i>(Américas, level E-2)</i>
	30 minutes		NRAs Rapporteur, TBD by moderator
	15 minutes		Regions Rapporteur, TBD by moderator
	25 minutes		Policy Makers Rapporteur, TBD by moderator
			Q&A and Discussion
16:00	20 minutes		Afternoon Break <i>(Foyer, level E-2)</i>
16:20			The Path Forward: The Global Action Plan to Increase Supply and Use of Influenza Vaccines of Assured Quality <i>(Américas, level E-2)</i>
	10 minutes	Session 13	Summary of key policy issues and options Dr. Daniel Miller, HHS/OGHA
	10 minutes		Summary of key strengths and gaps Dr. Endang Woro, DCVRN
	10 minutes		Next steps Mr. Lahouari Belgharbi, WHO
	10 minutes		Closing remarks by Brazilian National Health Surveillance Agency (ANVISA) Mr. Jaime César de Moura Olivera, ANVISA

* - In-depth discussion topics listed below

Session 5

Topics for discussion:

- 1) Communications between NRAs in the Region
 - a. What are the most effective communication channels?
 - b. What efforts do exist to collaborate and share information?
 - c. What has worked well in relationships between NRAs in the region?
2. Regulatory capacity in the Region
 - a. What are the critical regulatory capacity needs, gaps and strengths?
 - b. Were there any unique challenges faced by NRAs and policy makers in responding to the 2009 H1N1 influenza pandemic?
3. Establishment of coordinating and networking regional regulatory authorities
 - a. Are there opportunities for approaches and/or harmonization for regional regulatory decision-making?
 - b. What would be the pros and cons of the EMA-like model for developing countries in the region?
 - c. Can NRAs serve as training centers with experts to aid train other regulators in the region?
 - d. Are there any regional resources that can be leveraged?

*** - In-depth discussion topics listed below**

Session 8A

Topics for discussion:

- 1) Communications between in country-NRAs and policy makers
 - a. What have constituted effective relationships and communication channels between NRA and policy makers in your country?
 - b. What efforts do exist to collaborate and share information between NRAs and policy makers?
 - 2) Challenges faced by NRAs and policy makers in responding to the H1N1 2009 influenza pandemic
 - a. Examples of how established decision-making practices and priorities were challenged by the 2009 pandemic vaccine license and deployment?
 - b. For those nations where the government is the influenza vaccine supplier, were there ways to enhance the NRA's ability to have their own interpretation of data?
 - 3) Establishment of coordinating and networking between NRAs and policy makers at regional level:
 - a. Are there opportunities for approaches and/or harmonization for regional regulatory decision-and policy-making?
 - b. What would be the pros and cons of the EMA-like model for developing countries?
 - c. Can NRA and/or policy making body serve as training centers with experts to aid and train other regulators and policy makers in the region?
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Session 8B

Topics for discussion:

- 1) Communication and information sharing
 - a. What has worked well in relationships between NRAs and the policy makers in your countries?
 - b. What information do you use in your country to make policy decisions?
 - c. What information would it be beneficial for you to have in order to make policy decisions? Are you getting the information you need?
 - 2) Country's experiences with WHO vaccine deployment during the 2009 H1N1 pandemic (donors and recipients)
 - a. For those nations where the government is the vaccine supplier, are there ways to enhance the NRA's ability to have their own interpretation of data?
 - b. Examples of how established decision-making practices and priorities were challenged by the 2009 pandemic vaccine license and deployment
 - c. Implications of the public procurement process on vaccine capacity
 - d. Stewardship: the role of government in the face of market failure
 - 3) Establishment of coordinating and networking regulatory authorities and policy making authorities
 - a. What would be the pros and cons of the EMA-like model for developing countries?
 - b. The role of immunization advisory groups in promoting vaccine use
 - c. Public involvement in decision-making: enhancing the profile, credibility, and outreach of immunization advisory groups
 - d. National Preparedness Plans: explore the value of adding guidance for NRAs and vaccine campaign planning
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