## Agenda

### January 14, 2013

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>7:45 am – 5:00 pm</td>
<td>Registration And Information</td>
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<tr>
<td>8:45 am – 9:00 am</td>
<td>Opening Remarks</td>
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<tr>
<td></td>
<td>Marie-Paule Kieny, WHO</td>
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<td>Nils Daulaire, HHS</td>
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<td>Jon Andrus, PAHO</td>
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<tr>
<td>9:00 am – 9:20 am</td>
<td>Session 1: Welcome and Overview of Workshop Goals and Objectives</td>
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<td>Marie-Paule Kieny, WHO</td>
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<tr>
<td>9:20 am – 10:20 am</td>
<td>Session 2: Economics of Vaccines</td>
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|                 | **Presentation:** Economic characteristics of vaccines and vaccinations (20 min)  
|                 | Miloud Kaddar, WHO                                                     |
|                 | **Presentation:** General overview of business models – Fundamental principles of sustainability (30 min)  
|                 | Lisa Beth Ferstenberg, Johns Hopkins University                         |
|                 | Q+A (10 min)                                                           |
| 10:20 am – 10:50 am | Coffee break                                                           |
| 10:50 am – 12:20 pm | Session 3: National and Global Parameters Affecting Vaccine Manufacture Sustainability |
|                 | Moderator: Bruce Gellin, HHS                                           |
|                 | **Presentation:** The complex system for vaccine manufacturing (20 min)  
|                 | Bruce Gellin, HHS                                                     |
|                 | **Panel Discussion** – How governments/industry perceive the complex vaccine manufacturing system (50 min)  
<p>|                 | Feng Zhao, African Development Bank                                   |
|                 | Mahendra Suhardono, DCVMN/Bio Farma                                    |
|                 | Beverly Taylor, IFPMA/Novartis                                         |
|                 | Claudia Vaca, Ministry of Health, Colombia                             |
|                 | Witit Artavatkun, Government Pharmaceutical Organization Thailand      |
|                 | Q+A (20 min)                                                           |
| 12:20 pm – 2:00 pm | Lunch break                                                            |</p>
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<tr>
<th>Time</th>
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| 2:00 pm – 3:20 pm | **Session 4: Attracting Investments and Generating Revenue – Theory, Practice and Existing Business Models** | Moderator: Mike Watson, IFPMA/Sanofi Pasteur  
- **Presentation:** Valuing Vaccines and influenza vaccine economics (30 min)  
  *Peter Paradiso, Paradiso Biologics Consulting, LLC*  
- **Presentation:** Categorization of developing country manufacturers, existing business models and impact on markets (10 min)  
  *Miloud Kaddar, WHO*  
- **Case studies:** how does flu differ from other vaccines and how does this affects marketing? (20 min each)  
  - Sanofi Pasteur  
    *Michael Watson, Sanofi Pasteur*  
  - Commonwealth Serum Laboratories  
    *William Cracknell, CSL* |
| 3:20 pm – 3:50 pm | **Tea break**                                                             |         |
| 3:50 pm – 5:10 pm | **Session 4 – continued: Attracting Investments and Generating Revenue – Theory, Practice and Existing Business Models** | Moderator: Mike Watson, IFPMA/Sanofi Pasteur  
- **Case studies:** How does influenza differ from other vaccines and how does this affects marketing? (20 min each)  
  - Instituto Butantan  
    *Isaias Raw, Instituto Butantan*  
  - Bio Farma  
    *Mahendra Suhardono, Bio Farma*  
- **Panel discussion:** experiences in running businesses, in light of the company’s reference market (40 min)  
  *Marc LaForce, Serum Institute of India*  
  *Morena Makhoana, The Biovac Institute*  
  *Peter Paradiso, Paradiso Biologics Consulting, LLC*  
  *William Cracknell, Commonwealth Serum Laboratories*  
  *Isaias Raw, Instituto Butantan*  
  *Mahendra Suhardono, Bio Farma* |
| 5:10 pm – 5:20   | **Wrap up and Announcements**                                             | Marie-Paule Kieny, WHO  
  *Nils Daulaire, HHS* |
| 6:00 pm – 7:30 pm | **Welcome Reception at the Westin Georgetown Hotel**                     | (shuttles available)  
  Marie-Paule Kieny, WHO  
  Nils Daulaire, HHS |
## Session 5: The Impact of Technology and Method of Vaccine Production on Business Strategies and Opportunities
Moderator: Rick Bright, BARDA

- **Presentation:** Influenza Vaccine Production – Impact of technology, scale and other vaccines on financial viability (20 min)
  *Martin Friede, WHO*

- **Presentation:** Influenza technology compatibility/leveragability with existing/other vaccine investments in a single facility (15 min)
  *Josh Speidel, BARDA*

- **Case studies** on various technologies (and their business consequences) for influenza vaccine manufacturing (15 min each)
  - Serum Institute of India
    *Marc LaForce, SII*
  - Novartis Vaccines & Diagnostics
    *Beverly Taylor, Novartis*
  - China National Biotec Group
    *Qiyou Xiao, CNBG*

- **Panel discussion and Q+A** (25 min)
  *Martin Friede, WHO*
  *Josh Speidel, BARDA*
  *Marc LaForce, SII*
  *Beverly Taylor, Novartis*

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### Coffee break

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### Session 6: Innovative Models: Meeting Investment Demands While Addressing National And Regional Public Health Needs
Moderator: Mark Miller, NIH

- **Presentation:** Vaccine development: reducing risks, responding to demand: which Innovative models? (30 min)
  *Anthony So, Duke University*

- **Presentation:** BARDA international and domestic capacity building activities (20 min)
  *Robert Huebner, BARDA*

- **Presentation:** PAHO Revolving Fund: how it works, specificities for seasonal influenza vaccine, experience during the 2009 pandemic influenza (20 min)
  *Daniel Rodriguez, PAHO Revolving Fund*

- **Panel discussion open to the audience:** reflections on elements from case studies in Session 4, and how different models are relevant and appropriate for the country context, what are the possible synergies among the different models, and factors specific to pandemic preparedness (20 min)
  *Anthony So, Duke University*
  *Robert Huebner, BARDA*
  *Daniel Rodriguez, PAHO Revolving Fund*
  *Ruth Velasquez Fernandez, Laboratorios de Biologicos y Reactivos de Mexico*
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<tr>
<td>12:15 pm – 1:45 pm</td>
<td>Lunch break</td>
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| 1:45 pm – 2:30 pm  | **Session 7: National Regulatory Authority’s Role in Product Commercialization, Licensing and Innovation of Influenza Vaccines**  
Moderator: *Maria Pombo-Castro, PAHO*  
- **Panel discussion**: regulators’ perspective in supporting business development (45min)  
  - David Cho, FDA  
  - Carlos Matos Moreira, ANVISA  
  - Margareth Ndomondo-Sigonda, NEPAD/AMRH |
| 2:30 pm – 3:30 pm  | **Session 8 - Role and Impact of Networks**  
Moderator: *Martin Friede, WHO*  
- WHO influenza technology transfer (5 min)  
  *Martin Friede, WHO*  
- **Mission Statements**: How networks add value, and can contribute to regional and global public health efforts (5 min each)  
  - Developing Countries Vaccine Manufacturers’ Network  
    *Akira Homma, DCVMN*  
  - International Federation of Pharmaceutical Manufacturers & Associations  
    *Tamara Music, IFPMA*  
  - African Vaccine Manufacturing Initiative  
    *Patrick Tippoo, AVMI*  
- **Panel discussion**: Opportunities for partnership, market sharing, leveraging competition, managing conflict of interest, strategic alliances to compensate weaknesses and stimulate synergies, examples of how networks collaborate with other networks (40 min)  
  - *Akira Homma, DCVMN*  
  - *Tamara Music, IFPMA*  
  - *Patrick Tippoo, AVMI*  
  - *Makarim Wibisono, ASEAN* |
| 3:30 pm – 4:00 pm  | Tea break                                                                |
| 4:00 pm – 15:15 pm | **Session 9: The Role of National and Regional Planning for Influenza Pandemic Preparedness**  
Moderator: *Michael Perdue, FluSolutions*  
- **Panel discussion**: The role and importance of national and regional planning for influenza pandemic preparedness, and mechanisms and factors to consider (75 min)  
  - Bruce Gellin, HHS  
  - Brandon Manquin, McKinsey and Company  
  - Jean-Vivien Mombouli, Ministry of Health, Republic of Congo  
  - Trong Lan Phan, Ministry of Health, Viet Nam |
| 5:15 pm – 5:30 pm  | **Wrap up and Announcements**  
*Nils Daulaire, HHS*  
*Martin Friede, WHO* |
### Workshop on Business Modeling for Sustainable Influenza Vaccine Manufacturing

#### January 16, 2013

<table>
<thead>
<tr>
<th>Time</th>
<th>Session details</th>
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| 8:30 am – 9:40 am | **Session 10: Opportunities in a Changing World – New Markets, New Procurers, Better Risk Management**  
Moderator: *Nils Daulaire, HHS*  
- **Presentation:** New trends in the global vaccine market (20 min)  
  *Miloud Kaddar, WHO*  
- **Presentation:** Vaccines are not the magic bullet for pandemic Preparedness -- (20 min)  
  *Daniel Miller, HHS*  
- **Panel discussion:** statements and discussion about stakeholder’s views on the future and emerging opportunities (30 min)  
  *Miloud Kaddar, WHO*  
  *Daniel Miller, HHS*  
  *Michael Watson, Sanofi Pasteur*  
  *Morena Makhoana, The Biovac Institute*  
  *Jinchang Wu, BCHT Biotechnology* |
| 9:40 am – 10:10 am | **Farewell coffee** |
| 10:10 am – 11:25 am | **Session 11: Holistic Approaches/ Cross-Sectoral Policy**  
Facilitators: *Marie-Paule Kieny, WHO*  
*Bruce Gellin, GAP Chair*  
*James Fitzgerald, PAHO*  
*Daniel Miller, HHS*  
- **Open participant discussion:** Necessity of a supportive system and society, roles and responsibilities, future scenarios, possible engagements, pandemic preparedness (75 min) |
| 11:25 am – 12:00 pm | **Wrap-up and Closing remarks**  
- Introduction to next workshop (10 min)  
  *Daniel Miller, HHS*  
- Key messages from workshop discussions and closing remarks (25 min)  
  *Marie-Paule Kieny, WHO*  
  *Nils Daulaire, HHS* |