## Pan-American Network on Drug Regulatory Harmonization (PANDRH) - WG of Medicines Registration

### Workplan November 2010-July 2011

<table>
<thead>
<tr>
<th>#</th>
<th>Activity/Task</th>
<th>Responsible</th>
<th>Date</th>
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<tbody>
<tr>
<td>1.</td>
<td>Monthly Elluminate meeting</td>
<td>Secretariat</td>
<td>First Friday of each Month (TBC)</td>
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| 2. | Review and update the document on Requirements for Medicines Registration  
2.1. Request comments from Members of PANDRH  
2.2. To consolidate comments and to circulate a new version | Secretariat | 2.1. December/2010  
2.2. January/2011 |
| 3. | Develop the Guidelines for implementation of the requirements (including the glossary)  
3.1. Circulate the draft to the WG  
3.2. Deadline for receiving remarks and comments  
3.3. Consolidate comments and circulate the new version | Silvia Boni  
Secretariat | 3.1. Nov/2010  
3.2. Jan/2011  
3.3. Feb/2011 |
| 4. | Round of presentations of the state of the art in different Regional integration/economic Blocks  
• ASEAN  
• EMA  
• TBD | Secretariat | TBD (according availability of presenters) |
| 5. | Preparation for the VI PANDRH Conference  
5.1. To submit a new version of the Document of harmonized requirements and Guidelines to the Steering Committee (SC) for approval of the Conference  
5.2. Appreciation by the SC  
5.3. To circulate the document to the PANDRH members  
5.4. Presentation of the document during the conference | Silvia Boni  
Secretariat | 5.1. Mar/2011  
5.2. Mar/2011  
5.3. Jun/2011  
5.4. Jul/2011 |
| 6. | To prepare a workplan, including tools for implementing the proposal | Silvia Boni  
Secretariat | Mar to May/2011 |
| 7. | WG face to face meeting during the VI Conference | Silvia Boni  
Secretariat | Jul/2011 |
## Proposals to be considered for the development of the Workplan August 2011-July 2012

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<tr>
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<td></td>
<td>To review the monitoring and assessment indicators for Medicines Registration</td>
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<td>To prepare communication / information material</td>
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<td>Training based on the Guidelines on the Harmonized Requirements for Medicines Registration</td>
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<td></td>
<td>- Planning of the Training</td>
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<td>- Development of the training</td>
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<td>- Assessment of the training</td>
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