Workshop on Business Modeling for Sustainable Influenza Vaccine Manufacturing

Session 7: National regulatory authority’s role in product commercialization, licensing and innovation of influenza vaccines

Marcelo Moreira
Coordinator of Biological Products Licensing – CPBIH/ANVISA
Panel discussion: regulators’ perspective in supporting business development

Outline

1. Early involvement, framework for how to engage with manufacturers
2. Multi-product/purpose facilities
3. NRA timelines for qualification and response to companies
4. Pre-Qualification and considerations for entry into market
Early involvement, framework for how to engage with manufacturers

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New biological product

Individual route of development

Complete dossier

Biological product

Individual route of development

Complete dossier

Comparative Phase III

Comparability development

Comparability exercise

Quality, Safety, Efficacy

Non Innovative Biological Product

Biosimilar
Art. 49. The company applying for biological product registration may contact the Biological Product Coordination (CPBIH) to discuss aspects related to the product’s development before submitting the registration documentation, using the available mechanisms by the Agency.
Early involvement, framework for how to engage with manufacturers

- Pre-submission meeting
- Clinical Trials meeting (I/II)
- Phase I and II results review
- Phase III design and discussion

Research and Development Phase → Non-clinical → Clinical Trials Phase I and II → Clinical Trials Phase III
Multi-product/purpose facilities

1. Main vaccine producers to attend the “National Immunization Program” – PNI
   - Bio-Manguinhos and Instituto Butantan
Multi-product/purpose facilities

3. National strategy for blood products – Hemobrás
Technology Transfer as one of biological products development strategy

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<tr>
<th>Vaccine</th>
<th>Stage</th>
<th>Manufacturer</th>
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<tr>
<td>BCG</td>
<td>holds all technology</td>
<td>FAP</td>
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<tr>
<td>Polio (OPV)</td>
<td>imported API, formulation and filling</td>
<td>Bio-Manguinhos</td>
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<td>Yellow fever</td>
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<td>MMR</td>
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<td>Meningococcal A C</td>
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<td>Haemophilus influenzae B</td>
<td>holds all technology</td>
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<td>Tetanus toxoid</td>
<td>holds all technology</td>
<td>Butantan</td>
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<td>Diphtheria, tetanus</td>
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<td>Diphtheria, tetanus, pertussis</td>
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<td>Influenza</td>
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ANVISA is one of the actors in biological products development in Brazil – Technical Regulatory Committees

1. NRA from country that is transferring the technology
2. NRA from country that is receiving the technology
3. Producer from country that is transferring the technology
4. Producer from country that is receiving the technology

Assess and Address critical points during technology transfer
Pre-Qualification and considerations for entry into market

1. RDC 55/2010

2. Harmonized requirements for the licensing of vaccines in the Americas and the Guidelines for the preparation of application
Thank you for your attention!

“To protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance.”

Anvisa’s mission