Role of Partnerships in Developing Innovative Vaccines: Brazil

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Context

- Public sector (Unified Health System – SUS)
  - responsible for 95% of the national human vaccine market

- National Immunization Program (PNI)
  - Created in 1973 in order to offer and distribute vaccines to the Brazilian population
  - The State offers through this Program more than 15 vaccines:
    - BCG (intradermal); Hepatitis B; Oral poliomyelitis vaccine (OPV);
    - DTPw + Hib; Hib (*Haemophilus influenzae* b); DTPw (Diphtheria-Tetanus-Pertussis);
    - Influenza; Rotavirus Oral Human Vaccine – Monovalent G1 (P8); Yellow fever;
    - Measles-Mumps-Rubella (MMR); Influenza; Pneumococcal 10-valent
The vaccines that are offered to specific population groups

- Hepatitis A
- Hepatitis B
- Influenza
- DTPa (Acellular DTP)
- Pneumococcal 7-valent conjugate
- Pneumococcal 23-valent
- Inactivated poliomyelitis vaccine (IPV)
- Meningococcal group C conjugate
- Pentavalent (DTPw –Hib-Hepatitis B)
- Rabies
- Human immunoglobulins against hepatitis B
- Antitetanus
- Varicella-zoster (chickenpox)
Strategies for immunization actions

- PNI available infrastructure
  - 33,000 vaccination centers
  - 41 specialized immunobiological reference centers

- Some successful cases:
  - H1N1 pandemic influenza vaccine campaign
    - more than 85.3 million doses administrated
  - Rubella campaign in 2008: 96.75% coverage
Vaccination strategies

National Immunization Program/PNI: strategies

- **Routine**
  - ~33,000 vaccination centers
  - 39 Reference Centers for Special Immunobiologics (CRIE)

- **Campaigns**
  - Influenza (≥60 years) – 1 per year
  - Measles (<5 years) – follow-up every 4 years, or as epidemiological situation indicates

- **Control**
  - Outbreak response

Source: SVS/CGPNI/SES
Brazilian Vaccine Market

PNI vaccines are produced mainly by two state-owned (SO) institutions: Butantan Institute (São Paulo) and Bio-Manguinhos (Rio de Janeiro).

- There are three other producers:
  - Ataulpho de Paiva Foundation (FAP): BCG-ID (*Private non-profit*)
  - Ezequiel Dias Foundation (Funed): conjugated meningococcal C (SO)
  - Paraná Institute of Technology (Tecpar): rabies (animal use) (SO)

Public purchases encompass more than 90% of the Brazilian Vaccine Market.
Vaccines budget

- Routine PNI approved budget 2010
  - around US$ 1 billion/year in 2010, considering that, from all this amount, US$ 600 million are targeted as extra budget for campaigns and new vaccines:
    - H1N1 pandemic influenza vaccine (campaign)
    - Meningococcal group C conjugate vaccine (new on routine vaccination)
    - 10-valent Pneumococcal (new on routine vaccination)
Vaccine production

- Bio-Manguinhos and Butantan have technological and production process expertise for traditional vaccines:
  - Butantan Institute:
    - Hepatitis B, Influenza, rabies in cell culture, DT (for adult and children), DTP
  - Bio-Manguinhos:
    - yellow fever, DTP + Hib, Hib, Measles-Mumps-Rubella (MMR), OPV, rotavirus, Pneumococcal
Vaccine production targets

- Vaccine production targets on new technologies
  - New generation of vaccines
  - Process of antigen conjugation

- Priorities for complete technology transfer processes
  - Rotavirus, influenza, meningococcal A and pneumococcal

- Transfer agreements conditions (large tradition):
  - First step: incorporation of the final products
  - Second step: development through a logical step-wise process
  - Explicit deadlines, prices, markets and royalties
Research and development field

- Research predominantly related to clinical phases
- Some pre-clinical initiatives in-house
- Some established research on adjuvants
- Collaboration among manufacturers
- Two complementary strategies of development:
  - Autonomic research development
  - Technology transfer agreements
- New vaccines or combination of vaccines:
  - Rational vaccine application planning
  - Focus on reducing the number of injections
  - Ongoing project for a pentavalent vaccine (DTP + Hib + HepB)
  - Planning for a heptavalent vaccine (DTPw + Hib + Hepatitis B + IPV + Meningococcal), delivering seven antigens in only one injection.
THANK YOU!

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