WHO – HHS Workshop on Business Modeling for Sustainable Influenza Vaccine Manufacturing

Washington, DC     January 14th – 16th, 2013

Session 4: Attracting Investments and Generating Revenue – Theory, Practice and Existing Business Models
Prerequisites for a successful partnership with Health Authorities

Stakeholder needs

- Invest in health to invest in wealth to invest in health
- Prioritised expenditure + efficiency
- Decrease mortality, morbidity, individual, societal and economic impact
- Successful implementation of vaccination programmes
- Supply reliability/affordability + quality/safety + confidence
- Reliable demand forecasting to secure supply + funding

SP public health partnership strategy

- Sustainable & reliable supplier of quality vaccines + innovation
- Prioritised expenditure + efficiency
- Decrease mortality, morbidity, individual, societal and economic impact
- Promote integrated vaccine solutions, support implementation, measure progress [Partnership, supply data (IVS), financing (PIP) + Innovation (QIV)]
- Supply reliability/affordability + quality/safety + confidence & ToT when appropriate,
- Reliable demand forecasting to secure supply + funding

Rarely done well
We Play Different Roles in a Single Objective

Healthy Population = Healthy Economy

Shareholder
Best Return on Investment
(Profit)

Area of potential tension

Stakeholder
Best Value for Money
(Public Good)

Healthy economy = Healthy Population
How can we find this Goldilocks Zone?

**Ability to pay**
- **Not affordable to developer**
  - Price is too low to be a sufficient incentive for R&D and production
- **Not sustainable**
  - Price cannot act as a motor (be sufficiently high to cover costs & new investments)
  - Market becomes infertile:
    - Risk of market exit
    - No security of supply
    - Risk to quality

**Price**
- **Not affordable to purchaser**
  - Price as a barrier to access to vaccines
- **Not sustainable**
  - Price is too high for countries to plan long term campaigns
  - Reduction of the size of market & unpredictability of demand

**GOLDILOCKS ZONE**
- Bliss Point of Healthy Tension
- Reduce R&D & Capital costs Through co-funding
- Tiered Pricing
- Reduced COGs:
  - Innovation & efficiency
  - Low cost production site
  - Increased volume & demand predictability
- Increase value through capability & capacity building,
- Reduce buyer costs Through 3rd party co-financing
- Increase budget to reflect value of investment in vaccination
- Increase value through capability & capacity building,
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Mexico Case Study
Sanofi Pasteur
Mexico at a glance

- Population: 116.9 M inhabitants* (11th largest)
  - 13.3 M ≤ 5 years of age
  - 11.3 M ≥ 60 years of age

- High vaccination culture
  - Vaccination coverage has increased from 45% in 1980 to 95% in 2011
  - The Mexican Ministry of Health has a routine vaccination program and undertakes 3 National Health Weeks when target population is immunized

- One of the most complete public vaccination programs in the world
  - Acellular pertussis Penta vaccine
  - Rotavirus
  - Pneumo Conj
  - Influenza
  - HPV (women 11 years old)

- 85% of the vaccine market is public

* [www.conapo.gob.mx/es/conapo/proyecciones_de_lapoblacion_2010-2050](http://www.conapo.gob.mx/es/conapo/proyecciones_de_lapoblacion_2010-2050) (8/01/2013)
Long term commitment of the Mexican authorities for Influenza vaccination

- Influenza vaccination was included in National Immunization program in 2004

- Flu vaccination is free of charge in the public sector for the recommended population:
  - Children from 6 months of age to 5 years of age
  - For Adults from 60 and over
  - Healthcare workers
  - At risk population
  - Pregnant women

- Mexico: one of the largest demand for flu vaccines in the world:
  - Large Flu public market in Mexico: $2010 = 23.5$ Md
  - Projected to grow up close to $30$ Md by 2015 through new recommendations and coverage increase

- Flu, a national security theme for the government of Mexico:
  - Health authorities wanted self sufficiency of supply for interpandemic Flu seasonal or pandemic vaccines
Partnership a key success factor for our strategy in Mexico

- Sanofi Pasteur answered positively to Mexico authorities’ request by investing 100 Million Euros in a monovalent production manufacturing plant.

- In collaboration with a state owned company: Birmex
  - Interact as a reliable public health partner
  - Increase pharmaceutical manufacturing abilities in formulation, filling, packaging in a high quality standards environment
  - Scientific and technical knowledge / Know how
  - Improve time to market
The main stakeholders involved in the partnership

- **The Ministry of Health**
  - In charge of consolidating the recommendations from the CONAVA (vaccines experts committee) from the economical and logistical point of view
  - Responsible for the public vaccination program for the population that is not under a social security system (IMSS, ISSSTE)

- **Birmex**
  - A State owned company, MoH chairing the board
  - A producer of some vaccines such as OPV, Td, DTwP and anti scorpion and anti viper serums
Description of the agreement

- **Contract Birmex - MoH**
  - Secure enough supply of influenza vaccine to government

- **Contract Sanofi Pasteur - Birmex**
  - Technical support to adapt Birmex plant to enhance blending, filling and packaging influenza vaccine
  - Secure supply of influenza vaccine and the possibility to switch to pandemic monovalent vaccine if needed
Local production flow

30 M influenza doses
As of 2014

Sales to all Public institutions

BULK production + Quality Control in Ocoyoacac

FORMULATION, FILLING, LABELLING, Packaging, Quality Control and Release

NAME OF PRESENTATION
Tech Transfer Considerations
Global Capacity Out of Step with Demand

Doses distributed worldwide (millions)

Total Capacity

Real & Projected Demand

Market forces will not allow severe overcapacity to be sustained

Influenza Vaccine Supply and Demand, Oliver Wyman, Feb 2009

June 2012
Unpredictable and often high Cost

Current WHO funding: c.a. US$25M
Future financial requests: estimate US$51M
High Quality Influenza Manufacturing Requires Significant Investment.

- **MedImmune**
  - $55 million (75% USG / 25% Contractor), Retrofit an existing Influenza Facility

- **Sanofi Pasteur**
  - $168 million (75% USG / 25% Contractor), Retrofit an existing Influenza Facility

- **Novartis**
  - $1.8 billion (60-75% USG / 25-40% Contractor depending on phase of project), Cell Culture Facility (Holly Springs)
Conclusions

- We share the same goals
- Affordability and price are different things
- Many models to achieve the Goldilocks zone

Successful vaccine and vaccination business models require:

- Long term partnership
- Win-win situation for both parties
  - Sanofi Pasteur only produces in a small group of countries but given the commitment of the Mexican Government SP decided to invest in Mexico
  - Mexico has secured a privileged access to pandemic vaccine

- Transfer of Technology has many risks:
  - Failure rate is high
  - Cost of Goods is often high
  - The market will not support supply/demand mismatch for long
Thank you
It is Hard to Think of a More Sustainable Business Than Vaccines

- Life saving & improving, directly & indirectly
- Increased well-being, happiness & ability to benefit from education & opportunity.
- Capacity & capability building.
- Vaccines industry as driver of virtuous spiral of personal and economic health through:
  - Cost-saving prevention.
  - Biotech capacity, capability & employment building.
  - Invisible hand of economic health.
- Does not unsustainably consume or pollute.
- Eradicates pathogens.
- Reduces pathogen resistance.