Conference of the Developing Country Vaccine Manufacturers’ Network

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OBJECTIVES OF DVCNMN

- Ensure **consistent and sustainable** supply of **quality** vaccines at an **affordable** price to developing countries for their NIPs.

- Combat **IDs specific to developing world**, encourage (and support) R&D efforts; strengthening the capacity of vaccine producers in developing countries.

- Improve the **access of DCVMN members to technologies** necessary to improve the quality of their products.

- Develop **innovative models** of ownership of health related intellectual property.

- Assist members in **obtaining financing** for production.

- Facilitate the exchange of ideas and experience.

- Foster the development of members to **attain the status of WHO pre-qualification**.

- Promote participation of DCVMN members in **strategic planning and decision making related to vaccine** and health technology development and production and disease control policy.

Adapted from DCVMN website.
SUCCESS STORIES

• Created a niche in EPI vaccines; supply 43%* of vaccines GAVI purchases.
  – Currently together they meet 75% of vaccine needs of the developing countries

• Product development partnerships (PDPs) for new vaccines: DCVMN members play an important role in each one.
  – One more step towards self reliance

• Resource partners and “technology-hubs” have also played important role in technology transfers (IVI, NVI, WHO)

• Platform for periodically voicing opinion on regulatory requirements

*Source: GAVI alliance 2008
PDPs: MVP as an example

- Many more such partnerships are needed
- Helps strengthen the capacity in the emerging economies
Pneumococcal Vaccine development

PATH
Serum Institute of India
For PCV

PATH
Instituto Butantan
Children’s Hospital Boston
For pan-serotype whole cell vaccine

Panacea biotech Ltd, Shanta Biotechnics Ltd.
Both separate efforts towards PCV
Rotavirus vaccine development

Bharat Biotech International Ltd.
AIIMS, US-CDC, PATH

Shanta Biotechnics Pvt. Ltd
Serum Institute of India
NIH

Instituto Butantan
Cholera and Typhoid Vaccine Development

International Vaccine Institute

Transferred technology for both to many developing country manufacturers including

Shanta Biotechnics Pvt Ltd. (OCV and typhoid conjugate vaccine)
Vabiotech (OCV)

IVI also partnered with these manufacturers to generate evidence required by the policy makers for introduction of these vaccines.
Indian Vaccine Enterprise Today

Neglected diseases?
- Leishmaniasis
- Filariasis
- Helminthiasis
- Den- 3 companies
- TB: 2 companies

HPV: 4 companies, 3 have overcome IPR bottle neck

Flu: 3 companies, 4 different approaches (egg, cell, VLP)

Pncc: 3 companies, different TPPs and conjugation methods and carrier protein, Partnerships. 2 out of 3 are part of AMC supply to GAVI

Rota: 3 companies, 2 in-licensed from NIH, 1 indigenous

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DVCNM as a focal point-1

• For co-ordinating between local NRAs/NCLs and WHO

  – For developing fast track pathways for evaluating vaccines needed for emergencies (eg. H1N1).

  – Harmonized with the other global regulatory agencies
• Between WHO, IFPMA and other relevant bodies to bring about technology, knowledge and resource exchanges.

  – Should also communicate their technology needs to the local Governments.
WHO prequalification

- DVCNMN assists members, has majority of them WHO prequalified.

- WHO prequalification becoming more stringent for the newer, more complex vaccines.

- It is also **must** for all UN procurement.

- Therefore strengthening the NRA/NCL in sync with the WHO and other regulatory agencies becomes absolutely essential.

  - When should this be initiated for each vaccine?
  - How should it be done?
  - Technically sound manpower- ways to retain and incentivize is also important.
DCVMN as a focal point-3

• For developing technologies needed for emerging economies
  – Collaborate with appropriate research institutions through the Resource Partners, seek grants together
Role in NTAGIs and National Vaccine Policy

- Vaccine policy impacts uptake and thus market for vaccines
- DCVMN can contribute immensely to the NTAGIs and NVP of respective countries.
- Can contribute to and have consensus on generation of evidence required for policy making
- **TPP** of the newer vaccines depend a lot on such data (Pneumo, Rota)
Vaccine development is a risky venture: **Resource and Technology intensive**

Risk should be cushioned by appropriate funding from Government and International agencies

- **Partnership in the Development**?
  - In India SBIRI, BIPP, NIMITLI etc.

- **SEETOT** - Scheme to Enhance the Efficacy of Transfer of Technology (DSIR scheme)

- **Advance Purchase Commitments** from respective Governments and GAVI/UNICEF
Potential of vaccines to reduce deaths

Area of circles is proportional to the number of deaths (2008 data). Shaded areas are proportional to the number of deaths prevented by vaccination.

* Source: IVR strategic report 2010-2020
• Both disease burden and market size drive investment

• Both these elements aplenty in developing economies

• Multinationals are realizing the potential of VOLUME and engaging with developing country partners

**Challenge for DCVMN is to**

- Develop novel ways of technology transfers in sync with their goals.

- Broaden their ambit (of tech transfers) to include the vaccine giants without losing their vision of self reliance
Thank You!