Emerging Markets & Emerging Needs: Developing Countries Vaccine Manufacturers’ Perspective & its Current Status

by

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DEVELOPING COUNTRIES VACCINE MANUFACTURERS’ NETWORK

- an overview

- Formed in November 2000.
- 7 members Steering Committee.
- Full members of DCVMN are members with WHO pre-qualification located in countries with a fully functional National Regulatory Authority (NRA).
- Prospective Full (PF) members of DCVMN are vaccine manufacturers located in countries with a fully functional National Regulatory Authority working towards attaining the status of pre-qualification.
- Associate members of DCVMN are members who are committed to becoming viable and do not have a fully functional NRA but have the viability to supply to UN Agencies.
- Vaccinology Institutions (RIVM/NVI, IVI, NIH, Sabin etc) are resources for technical support. WHO helps with coordination of our network.
1) ANLIS/Argentina
2) Bharat Biotech Intl. Ltd., India
3) Bio Farma, Indonesia *
4) Biological E. Ltd., India
5) BioManguinhos/Fiocruz, Brazil *
6) BIRMEX, Mexico
7) China National Biotec Corp’n, China
8) CGEB, Cuba *
9) Dialian JGAD Bio-products, China
10) Finlay Institute, Cuba
11) Indian Immunologicals Ltd., India
12) Instituto Butantan, Brazil
13) IVAC (National Inst. of Vaccines & Biologicals), Vietnam
14) LG LifeSciences, Korea *
15) Panacea Biotech Ltd., India *
16) Queen Saovabha Memorial Institute (QSMI), Thailand
17) Razi Institute for Serums & Vaccines, Iran
18. Serum Institute of India Ltd., * India
19. The Biovac, South Africa
20. Vabiotech - Natl. Inst. of Hygiene & Epidemiology (NIIHE), Vietnam
21. VACSERA, Egypt
22. Xiamen YST Biotech, China
23. Zydus Cadila, India

Resource Institutes
a) RIVM/NVI  e) PATH
b) IVI       f) NIH
c) WHO      g) USAID
d) Sabin    h) PneumoADIP

* WHO Pre-qualified Vaccine Manufacturers
DCVMN – Mission

- To provide quality vaccines at affordable prices to the developing world, including vaccines required in developing countries and those in which there is limited interest to industrialized nations and, possibly, big pharma.

- To obtain recognition that developing country vaccine producers have an essential role in assuring availability of vaccines to immunize every child.
DCVMN – Strategic Goals

- International recognition such that developing country vaccine manufacturers have an essential role in assuring the availability of quality vaccines for national immunization programmes.

- Encourage continuation of R&D research and development efforts by full members to meet the emerging vaccine needs in the developing world.

- Foster the development of PF and associate members of the network to attain the status of WHO pre-qualification.

- Foster collaboration and communication amongst members of the network and actively participate in the international vaccine community to accomplish the network specified goals.
DCVMN – Objectives

- To provide a repository of information, such as an inventory of current and potential production capacities and facilitate information exchange amongst members.

- Training on Vaccinology.

- Facilitator for technology transfer.

- To provide independent laboratory support for members, projects and harmonize regulatory requirements.
DCVMN – Work Plan

International recognition such that developing country vaccine manufacturers have an essential role in assuring the availability of quality vaccines for national immunization programmes.

By collecting reliable information and profiles of each manufacturer and aggregate the information in order to make substantive pertinent statements to represent the network.

Active promotion of the achievements of network members to:

- GAVI
- UNICEF Supply Division
- Ministries of health or national procurement agencies and foundations/NGOs involved in national immunization.
- WHO
- The World Bank
Encourage continuing research & development efforts by full members to meet the emerging vaccine needs in the developing world.

Promote strategic partnerships amongst members and outside sources to expedite the development of emerging technologies leading to the introduction of new vaccines.

Responding to the demands of vaccine characteristics to improve immunization programmes.

Practice the proper transfer of technologies required to meet the needs of the developing countries.
Encourage the development of PF and associate members of the network to attain the status to WHO pre-qualification.

Create a platform for sharing experience and insight with PF and associate members to assist them with the process of pre-qualification.

Working with the Global Training Network (GTN) to make recommendations to meet the training needs of NRA’s and assist them in becoming fully functional.
Promote collaboration and communication amongst members of the network and actively participate in the international vaccine community to accomplish the network specified goals.

Direct the member elected to any external body to represent the interests, promote the priorities of the network and report information to the members through the SC.
PRE-QUALIFIED VACCINES CURRENTLY AVAILABLE FROM DCVMN


- Made available through UNICEF and PAHO and have private export markets.

- Most are expanding their capacities and adding new technologies including DTwP based combination vaccines with Hep.B & Hib.

- Have R&D efforts toward Rotavirus, Pneumococcal, Meningococcal and other vaccine needs.
NEW VACCINES UNDER DEVELOPMENT

Combination:
- BCG-HB
- Measles-Jap. Encephalitis
- Measles-Mumps-Rubella

Others:
- Pandemic Influenza
- Rotavirus
- Acellular Pertussis

Conjugated:
- Meningitis A-T
- Meningitis C-T
- Men A,C,Y,W
- Thyphoid-T
- Hib.-T
- Pneumococcus
NEW VACCINES UNDER DEVELOPMENT (Contd.....)

Recombinant/Chemical Synthesis:

- BCG-DPT
- BCG-Schistosoma
- Cholera
- HIV
- Malaria
- Pneumococcus PsaA PspA
- Schistosoma
- TB
International Agencies Expectations

- DCVMN manufacturer to develop all new vaccines e.g. Rotavirus, Pneumococcal, HPV, HIV, Influenzae, Malaria etc.
- Develop these vaccines in cGMP & WHO pre-qualified facility.
- Supply of all these new vaccines complying with international quality at lower prices than charged by existing developed countries vaccine manufacturers.
DCVMN Manufacturers’ Handicaps

- Access to the funds.
- Availability of proper infrastructure & R & D labs complying with GMP & GLP requirements.
- Latest production techniques & equipments.
- Availability of proper analytical methods and standards for the newer products.
- Trained technical staff.
- Finally most of the new technologies which are already under the IPR regimes are not available and they have to search for an affordable/non-infringeable technologies to move ahead.

All the above makes development of new vaccine very expensive in developing countries.
Way Out: DCVMN’s Expectations

- Financial support in terms of donations / soft loans for infrastructure development.
- Front-loading financing against the future commitments by the manufacturer.
- Support for conducting clinical trials as per current GCP norms.
- Full support to avoid immoral patents which unnecessarily delays the development of new products.
DCVMN’s Expectations

- Our members also expect financial support to buy patent rights for new technologies.
- Legal support to counteract litigations in developed world.
- Financial support for setting up Inhouse Power Plant using Green Technology to reduce their carbon footprint on the earth & to minimize waste.
DCVMN’s Position in International Arena

Although most International Agencies involve/invite DCVMN members in their meetings, there is no full-hearted support to promote the manufacturer, leave apart the new vaccines, but even for the existing vaccines, barring few exceptions.

General feeling of most of the members is that we get lot of lip sympathy, but not a concrete support from the international community.

If international community wants something concrete to be done, they can support the DCVMN members by helping as suggested above for which DCVMN will commit as follows.
DCVMN’s COMMITMENTS

- Making vaccines available in quantity & quality at affordable prices for the underprivileged children from the developing & also to the developed world.

- Meet the emerging markets and emerging vaccine needs in the developing world by continuation of R&D and developmental efforts by our members.
Specific Achievement by DCVMN

- 7 out of 28 members are WHO Prequalified for supply of basic EPI Vaccines to UN Agencies (*multinational suppliers have excited from this area*)
- UNICEF & PAHO procure more than 75% of their requirements of these vaccines from DCVMN. For certain vaccines (Measles & DTP Group) more than 90% supply is from DCVMN.
- Current supply of Polio Vaccine to UNICEF & also to Govt. of India is mainly from DCVMN members.
- *This means without DCVMN supply more than 90% new borns in the world will not have access to basic affordable childhood vaccines.*