

Developing Country Vaccine Manufacturers Network Perspective



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Developing Country Vaccine Manufacturers Network

- ❑ 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 (IVI, RIVM/NVI) are resources for technical support. WHO helps with coordination of our network.



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.**



Members

- 1) **Bharat Immunologicals & Biologicals Corp'n, India**
 - 2) **Bharat Biotech Intl. Ltd., India**
 - 3) **Bio Farma, Indonesia ***
 - 4) **Biological E. Ltd., India**
 - 5) **BIRMEX, Mexico**
 - 6) **Chengdu Institute of Biological Products, Baojiang, China**
 - 7) **China National Biotech Corp'n, China**
 - 8) **CGEB, Cuba***
 - 9) **Fiocruz/BioManguinhos, Brazil ***
 - 10) **Finlay Institute, Cuba**
 - 11) **Haffkine Bio-Pharmaceutical Corp'n Ltd., India**
 - 12) **Indian Immunologicals Ltd., India**
 - 13) **Instituto Butantan, Brazil**
 - 14) **Institut Pasteur d'Iran, Iran**
 - 15) **Institut Pasteur de, Dakar, Senegal***
 - 16) **Institut Pasteur de Tunis, Tunisia**
 - 17) **Institute of Virology, Belgrade, Yugoslavia**
 - 18) **Queen Saovabha Memorial Institute (QSMI), Thailand**
 19. **LG LifeSciences/Korea***
 20. **Lanzhou Institute of Biological Products, China**
 21. **National Inst. of Vaccines & Biologicals (IVAC), Vietnam**
 22. **Panacea Biotech Ltd., India ***
 23. **Razi Institute for Serums & Vaccines, Iran**
 24. **Serum Institute of India Ltd., India ***
 25. **Vabiotech, Natl. Inst. of Hygiene & Epidemiology (NIIHE), Vietnam**
 26. **VACSERA, Egypt**
 27. **Zhengzhou Kangtai Pharmaceutical Co. Ltd., China**
 28. **Zydus Cadila, India**
 29. **BIOVAC, South Africa**
- Resource Institutes**
- | | |
|---------------------------|------------------------|
| a) <u>RIVM/NVI</u> | d) <u>PATH</u> |
| b) <u>IVI</u> | e) <u>NIH</u> |
| c) <u>WHO</u> | f) <u>USAID</u> |



Contribution of DCVMN to UNICEF supply of vaccines

	Number of Pre-qualified Vaccine Manufacturers*	UNICEF Supply specific to Global Fund Purchase (Hep-B, Hib., DTwP-Hep-B, Penta, YF)	UNICEF Supply for basic EPI Vaccines excluding OPV
Industrialized Country Vaccine Manufacturers	9	73%	36%
Developing Country Vaccine Manufacturers	12	27%	64%
TOTAL :	21	100%	100%

* Note : Not all pre-qualified vaccine manufacturers submit bids to UNICEFs tender



Increasing the Access of developing countries to H5N1 vaccines: Potential DCVMN contributions

- Local manufacturing of influenza vaccine
 - Technology currently established only at one member company (Butantan, Brazil)
 - Several member companies actively seeking technology transfer to establish production

- Fill-Finish
 - A few partnerships in place for seasonal vaccine.

- Distribution



Establishing Production capacity at DCVMN member companies

- WHO has offered seed funding through a competitive grant

- Challenges:
 - Identifying technology-transfer partner
 - Medium to long-term solution: does not respond to immediate needs of developing countries

 - Sustainability: role of seasonal market ?



Prioritization of Pipeline

- ❑ **Developing countries have financial and infrastructure limitations for complete health care package.**
- ❑ **The disease burden of pre-existing infectious diseases is already very high & therefore the funds are prioritized only for urgent medical interventions.**
- ❑ **Both these features make these countries vulnerable for emerging diseases and more so to highly infectious pandemic diseases.**
- ❑ **Prioritize pneumonia vs flu**



R&D Capacity

- **Support required to meet challenges**
- **Minimal R&D capacity at DCVMN members**



R&D Capacity

- **The IP management / awareness in these DCVMN countries should require capacity building especially in relation to Pandemic flu**

- **Request from DCVMN to WHO :**
 - support capacity building

- **Request from DCVMN to local Governments :**
 - provide regulatory and disease burden



Conclusion

- **DCVMN is already providing the great bulk of vaccines purchased by UN agencies.**
- **With Catalytic support from the Global Community, DCVMN could establish capacity to access the H5N1 Pandemic vaccines.**