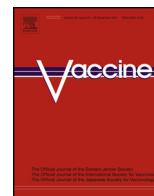




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## Conference report

### Developing Countries Vaccine Manufacturers Network (DCVMN): Engaging to step up for vaccine discovery and access. Meeting Report 2012<sup>☆</sup>

#### ARTICLE INFO

##### Keywords:

Vaccine  
Technology-transfer  
Manufacturing  
Public health  
Infectious diseases

#### ABSTRACT

At the annual general meeting of the Developing Countries Vaccine Manufacturers Network (DCVMN) members renewed their engagement and cooperative spirit in pursuing the mission of increasing the quality and availability of affordable vaccines for all people.

Thirteen years after its establishment, DCVMN moves into the Decade of Vaccines with renewed dynamism and synergy to create greater impact and shape the global and regional vaccination landscape, while supporting national growth. The DCVMN is growing: 12 new members joined in 2012, making a total of 37 members from 14 countries; 9 of these 37 manufacturers make WHO-prequalified vaccines.

More than one hundred and forty delegates from 23 countries attended the annual general meeting, representing 24 vaccine manufacturers and leaders of 20 major global health institutions. Over the course of two days, delegates exchanged information and ideas on how to jointly achieve the common goal of protecting people against known and emerging infectious diseases.

In an increasingly complex environment of new technologies, demanding regulatory requirements, higher cost of production, and a growing number of legal and intellectual property issues, it is observed that many manufacturers and stakeholders are engaged in technology transfer initiatives.

This well-attended meeting highlighted the growing impact and important contributions of developing country vaccine manufacturers in shaping the global vaccine landscape. The successful introduction of the first ever vaccine against hepatitis E and of a new vaccine against meningitis A, tailored for African meningitis belt countries, illustrate the innovative capacity of DCVMN members. An increase in the variety of collaborations, partnerships and alliances between DCVMN and various institutions was observed. Interestingly, bilateral technology transfer partnerships between DCVMNs themselves are on the rise.

## 1. Introduction

On the occasion of the Developing Countries Vaccine Manufacturers Network (DCVMN) annual general meeting, held from 31st October to 2nd November in Bali, Indonesia, members renewed their engagement and cooperative spirit in pursuing the mission of increasing the quality and availability of affordable vaccines for all people.

Thirteen years after its establishment, DCVMN moves into the Decade of Vaccines, with renewed dynamism and synergy to create greater impact and shape the global and regional vaccination landscape, while supporting national growth. The DCVMN is growing: 12 new members joined in 2012, making a total of 37 members from 14 countries; 9 of these 37 manufacturers make WHO-prequalified vaccines.

More than one hundred and forty delegates from 23 countries were present, representing 24 vaccine manufacturers and leaders of 20 major global health institutions, such as WHO, PAHO, UNICEF, IVI, GAVI, governmental agencies such as NIH, USAID, NIBSC, HHS,

RIVM, and NGOs including PATH, CHAI, AERAS, Hilleman Laboratories, and the Bill & Melinda Gates Foundation. They exchanged information and ideas on how to jointly achieve the common goal of protecting people against known and emerging infectious diseases.

The honorable Minister of Health of Indonesia, Dr. Nafsiah Mboi, addressed the audience with an inaugural speech specially recorded and delivered by video, encouraging the manufacturers to further engage in saving lives. The scientific programme addressed priority areas in order to further the Network's mission, including vaccine quality, influenza vaccine security, trends in international procurement and global access, strategic partnerships, innovation, and technology transfer.

## 2. Engaging for increasing vaccine quality

The opening session focused on standardization of vaccine quality control, with presentations by L. Slamet (Indonesian MoH), N. Dellepiane (WHO) and D. Buckley (consultant). It was chaired by S. Jadhav (SII) and co-chaired by D. Wood (WHO). Historically, vaccines were used for over one hundred years based on empirical experience, until a defective process of inactivating a subset of polio vaccines caused 40,000 cases of polio in 1955. This event, known as the Cutter incident [1], set a precedent for the regulation

<sup>☆</sup> Highlights of 13th Annual General Meeting of the Developing Countries Vaccine Manufacturers Network, Bali, Indonesia, 31 October–2 November 2012.

of biological products in the US, explained D. Buckley. Thereafter, good manufacturing practice (GMP) based on inspection of manufacturing processes was introduced, and became an integral part of vaccine regulation [2], which today enjoys a record of safety unmatched by any other medical product. Currently, GMP involves the inspection and testing of raw materials, calibration of materials and equipment, maintenance and planned preventative measures, quality control and sampling for quality assurance.

Improvements in specific areas, including validation and revalidation of biological analytical methods, suppliers/vendors qualification, media fills for finished products, change control systems, product quality reviews and personnel training, e.g. professional continuing education programmes on GMP, should continue, as improving knowledge at various levels through training is a promising future approach [3]. It was recommended to improve stringency, efficiency, accountability and transparency through strong training programmes for DCVMN members.

An update on WHO Prequalification (PQ) procedures was provided, focusing on a new aspect of programmatic suitability of product characteristics (PSPC) as reviewed by a new standing committee appointed in 2011 [4]. The committee will establish critical and desired programmatic vaccine characteristics, review currently prequalified vaccines and identify deviations from critical desired characteristics, and plans for corrections will be discussed with manufacturers on a case-by-case basis. Other updates were related to communication and transparency, through a web-based information channels for quality and safety issues, an upgraded list of PQ vaccines with detailed information on the products, publication of selected SOPs, WHO contracted laboratories for testing, introduction of PQ vaccines annual reports (PQVARS) including product safety updates reports (PSURs), and vaccine product assessment summary reports (VPASR). Additional features of WHO PQ services include encouraging meetings with manufacturers and pre-submission meetings between manufacturers and National Regulatory Authorities, reassessments based on risk analysis, compilation of all PQ data in a master database, and risk analysis. DCVMN supports the prequalification process. There were two WHO workshops for manufacturers in China and India, facilitated by DCVMN, to support achieving PQ. Finally, the expedite review procedure has accelerated registration of vaccines by NRAS. Notably, in 2010 the procedure was successfully used for the first time to register the meningitis A vaccine in three African countries. Since then, 11 other countries have used the procedure.

The controlled temperature chain (CTC) supported by the project Optimize [5] is another initiative intended to improve access to vaccines. This approach enables vaccines meeting specific stability conditions to be kept at ambient temperatures up to 40 degrees Celsius for one limited period of time immediately preceding administration. WHO encourages manufacturers to conduct thermostability studies to enable on-label use of vaccines in a CTC, and regulatory submissions following CTC guidelines and demonstration of impact [6].

### 3. Engaging in influenza vaccine global manufacturing security

A comprehensive strategy to improve access to influenza vaccines was discussed by M-P. Kieny (WHO) and D. Miller (HHS) chaired by M. Suhardono (Biofarma) and co-chaired by L. Slamet (Indonesian NRA). Evidence of local disease burden and vaccine efficacy are the drivers of national immunization policies. WHO recommends five priority groups for seasonal influenza vaccination, namely pregnant women, children under five years, health care workers, the elderly and people with underlying health conditions. Results of a survey in 2010 among 79 countries and territories

showed that national recommendations regarding influenza vaccination of these priority groups varies considerably. A survey of manufacturing showed that there is a total capacity for production of 1.4 billion doses. Half of this capacity is located in Europe, with zero capacity in Africa and the Middle East, and only 2% capacity located in South East Asia, where a large population resides. At present, 90% of the production technology is egg-based, but this is estimated to become more balanced within the next four years, with cell-based influenza vaccine technology becoming more available. More high-performance technologies are needed to secure global supply.

The global technology transfer initiatives to support pandemic preparedness were also discussed. In this context, over 20 million episodes of influenza-related pneumonia are reported annually, compared to around 13 million episodes of pneumococcal pneumonia, 8 million *Haemophilus influenzae* type b pneumonia episodes, and 33 million RSV pneumonia episodes, globally. Technology transfer to manufacture influenza vaccines in various countries will allow for timely access in case of a new pandemic. International initiatives coordinated by WHO and partners including the United States Department of Health and Human Services (US HHS) aim to expand capacity to make over 500 million doses of pandemic vaccines in developing countries. This will help to provide more equitable access to influenza vaccine. DCVMN members are actively engaged in these initiatives.

### 4. Engaging in international vaccine procurement and access

Global immunization strategies and access to vaccines were discussed by a group of experts and stakeholders including S. Hall (UNICEF), A. Nguyen (GAVI), D. Rodriguez (PAHO), and K. Bush (BMGF), chaired by M. Datla (BE) and co-chaired by S. McKinney (USAID). Annual deaths of children under five decreased globally from 12.4 million in 2000 to 7.6 million in 2010, however 19 thousand children are still dying every day from preventable causes [7]. UNICEF procurement for life-saving interventions increased to US \$2.14 billion in 2011, with US \$1.03 billion of that spent on vaccines. In 2011, 55% of those supplies are used in sub-Saharan Africa, 29% in Asia, 8% in the Middle East and north Africa, 5% in Latin America and the Caribbean, and 3% in eastern Europe.

Forecasting is a foundation for programmatic, financing, country supply, procurement, and production planning activities. There are now opportunities for UNICEF to benchmark data sources and uptake assumptions, as well as coverage, in alignment with strategic demand forecasting in collaboration with GAVI Alliance. New financing mechanisms have also exceptionally allowed pre-payments against very attractive pricing from manufacturers. Still, there is a need to find a balance between low pricing and returns for sustainable supply. Transparency is important for market efficiency, thus information is made available on the UNICEF website [8].

The Pan American Health Organization (PAHO) hosts a Revolving Fund (RF), launched in 1979, as the cooperative mechanism for vaccines, syringes, and related supplies procurement for participating Member States. The PAHO RF contributes to continuous supply of high-quality vaccines and uninterrupted procurement of commodities, as well as to catalyzing uptake of new vaccines, while keeping an orderly market with price stability and financial sustainability. The Americas have achieved the eradication of polio and elimination of measles, rubella, and diphtheria and control of pertussis, while DTP3 coverage continues to be a challenge in some areas. New vaccines such as pneumococcal and rotavirus have been introduced in 23 and 17 countries, respectively, and human papillomavirus vaccines were introduced in 4 countries. Further, seasonal influenza vaccines for the elderly were introduced in 39

countries. Today, the RF of PAHO covers 39 countries and territories with almost half a billion dollar purchase value and a \$100 million capital fund for 60 products and 28 antigens. It provides reliable forecasts, sustainable demand, and prompt payments to manufacturers. Current challenges are the supply of DTPw and yellow fever vaccines that are in shortage, requiring additional supply capacity.

Since its inception in 2000, GAVI has supported over 70 countries, contributing to strengthen the capacity of integrated health systems to deliver immunization while accelerating the uptake and use of new and underused vaccines. GAVI works with country governments to support national priorities, budget processes and decision making. It also plans to improve the predictability of global financing and the sustainability of national financing, with appropriate and quality vaccines as well as minimized costs to GAVI and countries. To date, pentavalent (DTPwHepBHib), pneumococcal and rotavirus vaccines have been approved to be introduced with approximately 160, 50 and 11 million doses, respectively, by 2015. Further, 32 countries are expected to introduce measles-rubella vaccines by 2015. Campaigns for meningococcal A conjugate vaccination in Africa started in Q4 2010, and will have vaccinated 100 million people by the end of this year [9]. Key facts and figures display GAVI's achievements to date as well as demonstrate its catalytic role within the global immunization landscape [10]. GAVI encourages competition, incentivizes new suppliers, and fosters multiyear agreements and innovative contracting methods. The DCVMN's goals are closely aligned to those of GAVI, which is reflected by DCVMN representation on the GAVI board and on its program and policy committee.

Vaccines also remain the highest priority of the Gates Foundation because of their ability to save millions of lives and their extraordinary impact per dollar spent. It was explained that the foundation accomplishes the majority of its work through partnership programs with industry and other global health stakeholders. Partnering with Industry is critical to achieving the Foundation's objectives because industry has the innovation, know-how, and critical mass of resources needed to best meet the toughest challenges in global health. Partnership program investments can be made in and with industry, reinforcing the value of science, innovation, and commitment provided by DCVMs as a means of meeting the needs of the world's poorest.

## 5. Challenges and opportunities posed by global regulations

In the following session, chaired by G. Harshavardan (Bharat) and co-chaired by N. Huda (adviser to Bangladesh MoH), D. Wood and S. Inglis (NIBSC) discussed the challenges and opportunities posed by global regulations. In 2009, an intergovernmental negotiating committee (INC) was requested by the UNEP Governing Council to prepare a global, legally binding treaty on mercury in order to reduce risks to human health. Current global discussions indicate that compulsory provisions on mercury usage might threaten access to thiomersal-containing vaccines, used as preservative in multidose vaccine vials. Based on information provided by WHO, there is, to date, no scientific evidence suggesting a possible health hazard. Removal of these products would disproportionately put in jeopardy the health and lives of the most disadvantaged children. WHO advised that pharmaceutical products should not be included in the treaty provisions on banning the use of mercury.<sup>13</sup>

Effective standardization of biologicals provides a strong regulatory support to industry, promoting accurate assay validation

and revalidation, and defining consistent dosing (potency), which has an impact on both disease burden as well as macroeconomic aspects of manufacturing [11]. The National Institute for Biological Standards and Control (NIBSC, UK) is keen in supporting individual DCVMN members and also the Network as a whole, in maintaining quality standards at a high level, to prevent any issues that could negatively impact vaccine coverage, as was the case in 1999 in the United States when concerns about thiomersal were raised [12]. International standard materials are available for the development of safe seed strains and suitable antigens, such as HIV, TB, influenza, meningococcal B, DTP, HPV, poliovirus, EV71, measles, mumps, rubella, and tetanus toxoid, for example.

## 6. Engaging in more partnerships, innovation, and technology transfer

The afternoon consisted of parallel sessions focusing on strategic partnerships and vaccine innovation technology. The discussions were led by R. Jain (Panacea), R. Barbera (Finlay), D.Y. Choi (LGLS), L. Leite (Butantan), E. Tsao (AERAS), Y. Wu (CNBG), H. Dabas (CHAI) and S. Gao (Innovax).

M-P. Preziosi (WHO/PATH) and M. Azizi (Pasteur Institute of Iran) delivered updated information on the way new vaccines impact on populations in need. M. Kaddar (WHO) and J. Chu, Clinton Health Access Initiatives (CHAI) elaborated on new challenges and opportunities in response to middle income country (MIC) needs and partnerships in improving vaccine introductions. There are 111 MICs with about 5 billion people and a birth cohort of 96 million. Globally, most poor people live in MICs, with significant diversity in burden of vaccine preventable diseases that, if ignored, can be a threat to their own—and neighboring—populations. Some MIC countries are not eligible for GAVI support which may have a negative impact on vaccine access: MICs contribute a large and stable share of the demand for vaccines. They also represent a potential market for underutilized vaccines, due to the increasing availability of local funding. Interestingly, there appears to be a trend amongst MICs to prefer combination vaccines in a single dose presentation. Also travelers from and between MICs are an increasing population. Entering MIC markets has unique challenges for new suppliers, as some countries are implementing more stringent regulation, procurement and financing procedures. To reach out, DCVMN should expand its market span in MIC countries.

Global partnerships can accelerate new vaccine introductions and advances in vaccine technology. Developing countries can adopt new vaccines at the same time as industrialized countries (for example, rotavirus vaccine in Nicaragua). Consequently, the cost for fully immunizing a child is ascending considerably, but varies among countries. This calls for a better global partnership and CHAI, among other established players of vaccine development and supply, is focusing on mitigating business risks, through investment cases and demand forecasting in Nigeria, Ethiopia, Malawi, Kenya and Tanzania.

M. Miller of Fogarty International Center (FIC) at the National Institutes of Health (NIH) introduced the opportunities available at NIH for expanding the vaccine portfolios of manufacturers. NIH supports vaccine research and development at various levels, from providing reagents and biological standards to supporting epidemiological and clinical studies, and technology transfer. Further information on vaccines is available through the NIAID website [13]. Highlights are the multinational influenza seasonal mortality studies, and novel conjugate typhoid vaccines.

D. Kristensen (PATH) introduced the Vaccine Presentation and Packaging Advisory Group (VPPAG), and encouraged DCVMN members to become involved in a dialogue with the VPPAG to facilitate

<sup>13</sup> A decision on this issue was made at the INC meeting (INC5), in January 2013, to allow the use of thiomersal (ethyl-mercury) as a preservative in human and animal vaccines. Cf. [http://www.who.int/mediacentre/news/statements/2013/mercury\\_20130119/en/](http://www.who.int/mediacentre/news/statements/2013/mercury_20130119/en/).

## Partnerships steps for Technology Transfer in Global Health



**Fig. 1.** Schematic illustration of the sequential phases that are followed to increase access to vaccines in developing countries. Stakeholder groups, as exemplified by academic groups university of Lausanne, public health agencies WHO, governmental RIVM and non-governmental international organizations IVI, and developing countries vaccine manufacturers, are engaged in technology transfer initiatives, from laboratory research, human clinical trials and manufacturing process optimization to supply.

improvements in vaccines presentation and packaging that can increase the uptake of vaccines. Current projects are label standardization and bar-code use. N. Havelange from European Vaccine Initiatives (EVI) encouraged DCVMN members to take up industrial development of vaccine candidates after phase 1–2 clinical trials. EVI's mission is to contribute in global efforts to control diseases of poverty, and it operates as a funding agency with a clear service-oriented strategy in pharmaceutical and clinical development of vaccines. C.Loucq (IVI) discussed the two available prequalified oral cholera vaccines, and a five-year outlook to accelerate introduction in endemic countries and establish a stockpile [14] to prevent between 1–2 million cases and save up to 86 thousand lives [15].

J.-M. Preaud (PATH) presented a new live bovine-human reassortant rotavirus (BRV) vaccine that is both affordable and effective in developing countries. The new vaccine could protect against four of the most common strains and two others frequent in Asia and Africa. The BRV is licensed by NIH to a number of manufacturers in emerging countries. PATH has delivered considerable support to BRV manufacturers, ranging from facility design and training to clinical validations.

C. Hendriksen from the Netherlands Vaccine Institute (NVI) spoke about current and future approaches to lot release testing in Europe, using alternative assays to reduce animal use.

N.Collin (University of Lausanne) emphasized that public health needs can exceed global antigen production capacity, e.g. in case of epidemics or emergency situations, and that adjuvant-sparing technologies represent an option to increased availability and affordability of vaccines [16].

In the final plenary session of the conference, chaired by A. Homma and C. Loucq, speakers shared their understanding, experience and prospects on technology transfer.

In a retrospective, J. Hendriks reviewed technology transfer as one of the main factors that has shaped the developing world vaccine industry [17]. In an increasingly complex environment of new technologies, demanding regulatory requirements, higher cost of production as well as a growing number of legal and intellectual property issues, it is observed that many stakeholders, including WHO, NGOs, DCVMN, and other manufacturers are engaged in technology transfer initiatives, from laboratory, human clinical trials and manufacturing process optimization to supply (Fig. 1). In this area, RIVM has made a significant contribution to the developing country vaccine industry by developing vaccine candidates and working with DCVMs in new partnering opportunities, linking academic research and public health agencies to industry, specifically to increase access to polio, influenza and *Haemophilus influenzae* type b vaccines.

M.Makhoana (Biovac) noted the scope and the benefits of technology transfer, and illustrated the success factors that characterize a win-win technology transfer case, including a clear outline of goals and expectations, the complementary abilities

of partners, regulatory know-how, manufacturing infrastructure, technical competency, financial ability and human capital. Ideally, partners involved in a technology transfer will aim that products achieve sustainable supply, know-how transfer and public health impact on disease burden. Technology transfer should increase affordability.

P. Huirong illustrated the innovative new technology platform from Xiamen Innovax Biotech and Xiamen University in China. They have successfully developed a recombinant *E.coli*-based virus-like particle (VLP) vaccine against hepatitis E, recently launched in China. Safe and cost-effective technologies tailored for this system, including protein purification, in vitro assembling, and VLP quality control have also been developed. A new vaccine candidate against HPV16 and 18 has proceeded to phase II clinical trials. In addition, the hepatitis B virus core antigen and a rotavirus VLP can also be assembled based using this system.

## 7. Concluding remarks

In conclusion, this well-attended meeting highlighted the growing impact and important contributions of developing country vaccine manufacturers in shaping the global vaccine landscape. The successful first introduction of a new vaccine against hepatitis E by a DCVM illustrates the innovative capacity of DCVMN members. An increase in the variety of collaborations, partnerships and alliances between DCVMs and various institutions was observed. Interestingly, bilateral technology transfer partnerships between DCVM themselves are also increasing. At this meeting, M. Suhardono from Biofarma, was elected as new DCVMN President for a term of two years, and representatives from China were elected as executive committee members, reflecting the global engagement of China's vaccine industry. The 2013 Annual General DCVMN meeting will be hosted in Vietnam.

## Acknowledgements

We are indebted to all speakers and moderators, whose valuable contribution made the conference possible. We appreciate the contribution of the rapporteurs, A. Gholami, J. Hendriks, W. Huang, who helped in drafting parts of this report. We are grateful to J.-M. Preaud and D. Brigden for review and help with editing. We thank corporate partners for support to the meeting with unrestricted educational grants: MerckMillipore, Bioengineering, Pall, Marchesini, Applikon.

**Conflict of interest:** The authors are employees of the respective indicated organizations, and have no conflict of interest to declare. DCVMN International did not provide any financial or travel support to speakers or moderators to participate at this meeting.

**Important note:** This report summarizes the views of an international group of experts as presented at a scientific conference in



a given timepoint and context, and does not necessarily represent the decisions or the stated policy of any institution or corporation.

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11 April 2013

17 April 2013

29 April 2013

Available online 15 May 2013