Vaccine xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Conference report

Better vaccines for healthier life. Part I. Conference report of the DCVMN International 14th Annual General Meeting Hanoi, Vietnam☆

ARTICLE INFO

Keywords:
Polio-eradication
Infectious-diseases
Immunization
Public health

ABSTRACT

The Developing Countries Vaccine Manufacturers' Network (DCVMN) brought together nearly 220 senior representatives of governmental and non-governmental global health organizations, as well as corporate executives of emerging vaccine manufacturers, from 26 countries for a two-day tailored lectures, Q&A sessions, CEOs panel discussion and networking opportunities, followed by a vaccine-technology symposium and visit to manufacturing facilities in Hanoi, Vietnam. Participants included representatives of 38 vaccine manufacturers, as well as international partners and collaborating research institutions, with 39% female participants. The Vice-Minister of Health to Vietnam commended the speakers and participants to this Annual General Meeting, devoted to achieve our common goal of protecting people against infectious diseases with better vaccines, for a healthier life. He reminded the audience that the first vaccine produced in Vietnam was oral polio vaccine (OPV) in the early 1960s and contributed to polio eradication in Vietnam, in 2000. Through its manufacturing resources, Vietnam eliminated neonatal tetanus in 2005, and has controlled measles and hepatitis B spread. The Ministry of Health hopes that by sharing experiences, delegates at this conference will foster international cooperation and partnerships among organizations. CEOs elaborated on challenges and opportunities for emerging countries.

1. Introduction

The conference was opened by DCVMN President, M. Suhardono, by acknowledging Vabiotech, the host of this event, and the government of Vietnam, for their engagement in vaccine manufacturing and for their hospitality towards the international members and stakeholders. The Honourable Vice-Minister of Health of Vietnam, Mr. Nguyen Thanh Long, stated that the Vietnamese Government and the Ministry of Health strongly support the vaccine manufacturing system in the country. Over the past 25 years, the National Expanded Programme on Immunization has achieved significant results by changing disease patterns in children. There are now four major vaccine manufacturers in Vietnam, namely VABIOTECH, POLYVAC, DAVAC, and IVAC. The local manufacturers supply so far ten out of eleven vaccines for the National Expanded Programme on Immunization in Vietnam including the licensed oral polio vaccine, DTP, BCG, Japanese encephalitis, hepatitis B, cholera, typhoid fever and measles vaccines. The vaccine manufacturers in Vietnam count many new vaccines under evaluation or licensure such as rotavirus, A/H5N1 influenza, seasonal influenza, dengue, and combination vaccines.

2. Global public health needs and challenges

B. Aylward, from WHO, gave a key note lecture focusing on the Global Polio Eradication strategy. Since the Polio Eradication programme started, in 1988, the number of polio-paralyzed children has decreased tremendously, from an estimated over 350,000 children paralyzed every year to a few hundreds in 2013, due to vaccination, and poliovirus type 2 has been eradicated, in 1999. However, between 2000 and 2011, 14 countries reported circulating vaccine-derived (type 2) poliovirus outbreaks. While India stopped transmission in 2011, cases were alarmingly increasing in Nigeria, Afghanistan and Pakistan during the same period. Thus on 25th May 2012 the World Health Assembly declared polio eradication an emergency for global public health and urged WHO to rapidly finalize a Polio Endgame Strategy. A key element of the endgame is the removal of the type 2 component of the oral poliovirus vaccine, facilitated by the introduction of an affordable inactivated injectable polio vaccine (IPV) globally. A study conducted in Cuba reported a breakthrough in the search for an 'affordable IPV' with one fifth dose of IPV found to achieve 63% seroconversion, and 99% priming against poliovirus type 2 [1]. This result was crucial to a landmark SAGE recommendation that all countries should introduce at least one dose of IPV into their routine immunization programmes to mitigate the risks associated with withdrawal of OPV2. To date in 2013, no type 3 polio virus cases have been detected for the first time in history, and there has been a nearly 50% decrease in endemic virus cases in Afghanistan, Nigeria and Pakistan. Still reports of spreading of viruses to Egypt,

☆ Important note: This report summarizes the views of experts as presented at an international scientific conference in a given time point and context, and does not necessarily represent the decisions or the stated policy of any institution or corporation.

0264-410X/$ – see front matter
http://dx.doi.org/10.1016/j.vaccine.2014.05.075

Israel, and Somalia are of concern and are challenging eradication resources.

The Polio endgame goal is to complete eradication and containment of all wild and vaccine derived polio viruses, with a global plan that has four objectives [2], the second of which is particularly important for vaccine manufacturers: OPV2 withdrawal and IPV introduction in 125 countries within 24 months. New partners are helping with both interruption of wild poliovirus transmission and implementation of the new endgame strategy, with the Red Cross/Red Croissant movement and GAVI being particularly important examples. 14 countries, representing 61% of the OPV-using population in the world are the priority for IPV introduction. In the near future the eradication effort will also need a robust supply of monovalent OPV type 1, bivalent OPV type 1&3, and trivalent OPV; bivalent OPV needs to be licensed for routine use as part of the strategy for removing OPV2, and OPV type 2 withdrawal is planned for as early as 2016. The world still needs new low cost IPV formulations and new devices to improve immunization.

T. Mundel provided a key note lecture on the importance of industry partnerships and delivery focused innovation in global health, as well as an update on the Bill and Melinda Gates Foundation (BMGF) evolving strategies around its three major areas of focus programmes: global health, global development, and United States programmes. The Foundation's mission is to distribute funds most efficaciously, with a 2012 budget of 3.4 billion dollars dedicated to over 1200 programme related investments grants, including 600 million dedicated to R&D and 400 million to delivery projects. Over the last decade the number of manufacturers supplying vaccines for the poorest GAVI funded countries doubled with DCVMs participation, and today two thirds of children worldwide get vaccines from DCVMs. A 36% drop in cost to fully immunize a child with Pentavalent (DTPHepB-Hib), Pneumococcal conjugate vaccines (PCV), and rotavirus vaccines (from 35 to 22 USD) has been realized over the last decade. Mortality of children under 5 years old decreased from 20 million in 1960 to about 7 million in 2012. Neonatal and nutritional disorders have decreased in the Americas but still not in Africa and Asia.

Thus, Dr. Mundel emphasized that partnerships are important and innovation in vaccine financing is critical and is also enabling to save more lives. "Programme Related Investments" (PRIs) are increasing in scope and size. As an example, a new Global Health Investment Fund of 100.000 million dollars was launched in 2013 primarily for the purpose of providing funds for late stage clinical trials, and is open to industry, individual and institutional investors. The foundation's PRI programmes are focused on the development of drugs, vaccines, diagnostics, and other interventions for low-income countries. It includes but is not limited to fund investments, equity investments, loans and guaranties. An example of innovative global partnership to end deadly meningitis type A epidemics in Africa is illustrated by the development and low cost per dose of a meningitis A vaccine. A two-pronged introduction strategy included mass campaign vaccinations to gain immediate benefits, and vaccine integration into routine childhood immunization programmes, with over 100 million people immunized since 2010. He said that the Foundation is committed to enabling strong partnerships for innovations in vaccine development with DCVMs, to support new candidate vaccines, such as new conjugation technologies, new adjuvants technologies, process development technologies, and to facilitate the provision of scientific, technical, and regulatory advice to manufacturers to minimize regulatory delay and speed access to needed products, and improving incentives for the Prequalification (PQ) process for critical vaccines.

3. Global vaccines procurement and supply

M. Shirey gave an update on UNICEF supply division activities related to vaccines. UNICEF procures vaccines and immunization supplies on behalf of around 100 countries annually and 1.89 billion vaccine doses were delivered through 1946 shipments in 2012, including 0.78 billion doses procured from DCVMs with a value of US$338 million (32% of total value of US$ 1, 053 million). The majority of the value of procured vaccines reflect PCV (ca. 40%), Pentavalent (ca. 30%) and OPV (ca. 15%) [3]. UNICEF's procurement is aimed at achieving Vaccine Security – the sustained, uninterrupted supply of affordable vaccines of assured quality.

UNICEF requests for proposals include multi-year tender and award period providing planning horizon and more certainty to manufacturers. Awards and Long Term Agreements are based in 'good faith' framework agreements, and on accurate forecasts, but treated as contracts. To achieve exceptional results exceptional contracts have been awarded, such as firm or pre-paid vaccines, when a funding partner has agreed. Generally, multiple suppliers are awarded per product and pipeline is assessed in award recommendation, to incentivize continued market development.

For instance, OPV supply is going to be extremely tight through to mid-2014, and UNICEF has contracts in place for 2013–2016/2017, while conducting a multi-year tender (2014–2017/2018) to secure sufficient supply of IPV to meet the Polio Endgame timelines, and achieve affordable pricing. An IPV tender was issued on 4 October that includes a sub-set of 124 OPV-using countries and up to 404 million doses requested.

For Pentavalent, there are expectations of 180 million doses supplied annually, fully awarded for 2013–2014, with some quantities not awarded for 2015–2016, as other demand for Middle Income Countries (MICs) (annual tender) and expansion in India are expected.

Regarding PCV, a third call for offer was concluded on July 2013, securing 50 million doses annually, increasing total supply to 146 million doses from 2016 onwards. There are still 405 million dollars out of $1.5 billion of Advance Market Commitment (AMC) funds available for future awards to contribute to the AMC objective of creating a healthy vaccine market including multiple manufacturers. Thus manufacturers with pneumococcal vaccines in development should register to the AMC to have supply offers assessed, if supply is envisaged within 5 years.

There is a need to rapidly expand the supply base of prequalified rotavirus vaccines to continue accelerate introductions and to meet projected future demand. UNICEF tendered for 88 million courses of rotavirus vaccines for the period 2012–2016, and 71 million courses have been awarded to two suppliers with prequalified vaccines while additional awards are to be made based on available supply and new country demand. Rotavirus vaccine demand is higher than supply (29 countries approved with GAVI support with 10 country introductions, procuring through UNICEF) with 90% of demand for one vaccine using a two dose schedule, resulting into scaling up of supply while requiring countries to delay introductions, and reduced vaccination cost per course. Human Papillomavirus (HPV) vaccine demand from GAVI 56 countries may reach 39 million doses by 2020, and first tender was awarded in 2013 to cover 10 demonstration programmes and 1 national introduction. Peak demand for Measles-Rubella (MR) is forecasted to occur in 2017–2018, but will depend on actual country plans, if delayed Measles demand will increase.

UNICEF is experiencing an increase in countries requiring national licensure. The National Regulatory Authorities (NRA) of importing country need to undertake an oversight role. An increasing number of countries also accept WHO Procedure for Expedited Review of Imported Prequalified Vaccines for Use in National Immunization Programmes. [4] UNICEF is working with

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governments, donors, and suppliers to support MICs purchase of affordable vaccines, particularly for HPV, Rotavirus and Pneumococcal vaccines, based on indicative interest from 24 MICs. In addition, separate annual tender for Pentavalent vaccines, as well as demand for IPV is included in tenders for MICs. [5]

D. Rodrigues provided an update on the Revolving Fund of the Pan American Health Organization (PAHO) for the procurement of vaccines for the region of the Americas. This is the leading region for elimination and eradication of infectious diseases, notably of polio, measles and more recently rubella. New vaccines have traditionally been rapidly and largely introduced in American countries, for instance with 90% of the birth cohort in the Region is in countries that include the pneumococcal vaccine in its regular programme (60% of the cohort of LAC[1]), 87% of cohort is living in countries that already use rotavirus vaccine (60% of the cohort of LAC) and 58% of girls 10–14 years old live in countries that have the HPV vaccine. Four components may have contributed to this regional success: (a) vaccines are declared as public good, (b) there is commitment and solidarity to achieve regional goals, (c) continuous availability of high-quality vaccines, through the Revolving Fund, and (d) vaccination is highly accepted by populations in Latin America. In the region of the Americas, more than 95% of the funds used to cover the operating expenses of the immunization programmes, including the procurement of vaccines, are funded with national budgets. Also the majority of countries already have immunization laws in place (Fig. 1).

To date 15 vaccines are recommended to be included in the national immunization programmes in the Americas[2]. For example, influenza vaccines had greatest uptake in this region of the world with 40 countries adopting seasonal vaccination, with majority for elderly, health workers and persons with chronic diseases, and approximately half of the countries offering vaccination to pregnant women and children. The PAHO Revolving Fund represents for manufacturers a "single window" to access 40 countries, a vaccine market with sustainable demand, prompt payment, post marketing surveillance, among other features. Also 60 days credit line to countries supports promptly placement of purchase orders. Presently there are needs for yellow fever supply, varicella and DTaP. Also the Region represents an opportunity for increasing competition for seasonal influenza, PCV, Rotavirus, and HPV vaccines.

M. Malhame presented the GAVI Alliance Vaccine Investment Strategy update, which is the mechanism to make decisions for support to introduction of vaccines in the poor countries financed by GAVI. In 2008 the GAVI board asked for a comprehensive process, instead of case-studies, as in the previous years to define the funding portfolio. Based on analytical data, including demand forecast, and technical and country consultations, surveys and interviews with stakeholders along the last 12 months, 15 vaccines were reviewed according to demand, cost, impact and other features. Five vaccines were prioritized: malaria and maternal influenza based on to public health impact, cholera and yellow fever based on epidemic potential, and rabies based on cost-effectiveness (cost per death averted). The prioritized vaccines were discussed at the board meeting on November 21st, and two vaccines were selected: malaria, cholera stockpile and additional yellow fever campaigns. GAVI will reevaluate the vaccine landscape in 2018.

The speakers, moderated by K. Bush and M. Datla, discussed the challenges of global vaccines' procurement. K. Bush acknowledged

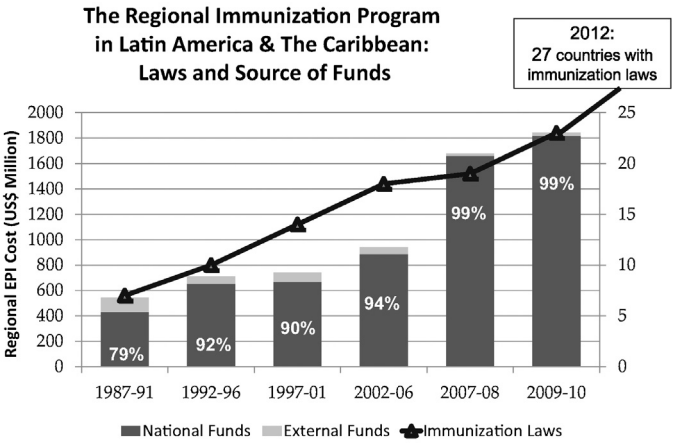

Fig. 1. Chart depicting the costs in millions US dollars (left scale) and percentage of the expanded programme on immunization (EPI) funded by national budgets (in percentage) from the 1990s until 2010, and the number of countries with immunization laws (right scale), among the 48 countries or territories in the American continent. The immunization programmes in the Americas are recognized as successful for eliminating infectious diseases and achieving high vaccination coverage, but also on achieving financial sustainability and having a high political commitment. Even with an increase in immunization costs over the years, particularly in 2007–2008, national budgets increased their participation to reach 99% in 2010. In 2012, 27 of the 48 countries/territories had immunization laws available that declare vaccination as a public good, free of charge to the population, secure budgets and define the procurement mechanisms for vaccines.
Courtesy of D. Rodrigues.

the DCVM group for commitment and investments in vaccines manufacturing, and mentioned that the BMGF works through partnerships: there is no purchase, no storage, but help through not-for-profit partners. He explained that the life sciences group at the Foundation focuses on industry partnerships for a deeper and broader engagement and understand the industry capabilities and sustainability of goals. The group has dedicated resources for working with multinationals, biotech, and DCVMs that have different operating models and expectations. Another group working with vaccine policy groups supports the interface between supply and demand. He added that criteria to select industry partners include: (1) corporate business strategy overlapping programmatic needs of EPI vaccines; (2) availability of a technology platform to operate supply such as GMP compliance and a culture of continuous quality improvement; (3) access to know-how and scale-up expertise as well as innovation to match affordability; (4) history of financial sustainability; (5) programmatic demand knowledge to run a sustainable business; (6) equity in biotech industry. Still the Foundation has the flexibility and ability to be creative and welcomes innovative proposals.

D. Rodriguez added that the PAHO Revolving Fund is now focusing on vaccine affordability rather than on security, and thus agreements are on an annual or biannual basis, rather than long-term multiyear agreements like UNICEF. The large majority of member States in the Americas use their own funds to acquire vaccines, and pool procurement is based on solidarity with small countries that would not have access to good deals if out of the pool. M. Malhame added that GAVI engages with manufacturers and donors through an open dialogue on potential demand, including the industry in the discussions of forecast and roadmaps for vaccine introduction. Limited vaccine supply is often a challenge, meant D. Rodrigues, such as presently Yellow Fever (YF) vaccine supply shortage. Despite four YF manufacturers the demand is not met, due to cumbersome technology and the lack of incentives to larger volumes' supply, despite some signal of expanded campaigns to come. Another challenge is an imbalance created by increased

[1] Latin America & The Caribbean (LAC).
[2] BGC, DTP, Hib, HepB, Polio MMR, Yellow Fever, Influenza, PCV, Rota, HPV, Pneumo23, HepA, varicella and meningitis.

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Pentavalent demand in some countries that could result in shortage of DTP for other countries.

A concern to manufacturers of developing countries is the increasing requirements for registration in individual countries, delaying access, even when vaccines have gone through prequalification, while the tools and instruments exist to expedite registration.

4. Pathways for access to vaccines

P. Duclos presented WHO's Strategic Advisory Group of Experts (SAGE) on immunization, which issues global policy recommendations and strategies to supporting regional/national challenges. SAGE recommendations have an impact on countries' vaccination policies, global partnerships, regulatory processes, vaccine demand and vaccine supply by industry. The technical advisory committees and working groups provide evidence to inform the global policy recommendations and strategies of SAGE that can be adapted and implemented, within the local epidemiological and socio-economic context, at regional and national levels. SAGE working groups, composed by SAGE members and additional independent experts, are established to review evidence and address specific issues in great depth and prepare for fruitful discussions at plenary SAGE meetings. Issues taken into consideration by SAGE include disease epidemiology, vaccine characteristics, clinical and immunization features and economic considerations. Additionally, health system opportunities and other existing interventions and control strategies, social impact, legal and ethical issues are also considered. However, information on alternative immunization schedules, vaccines co-administration, risk groups or (post-marketing) surveillance data is often lacking to support decision making. The WHO vaccine position papers, available in English, French, Arabic, Chinese, Russian and Spanish, summarize the recommendations of SAGE and serve as key reference documents. [6] Comments from vaccine manufacturers to the position papers are sought through e-consultations, while aware of potential conflicts of interest and equity. SAGE has also provided guidance to vaccination in humanitarian emergencies, based on assessment of the epidemiological risk, vaccine characteristics, and prioritization in the context of other urgent public health needs and security, financial, and political realities. New SAGE working groups will be formed to review evidence leading to updating recommendations on the use of Japanese encephalitis, pertussis, varicella, hepatitis E, and malaria vaccines among others.

N. Dellepiane gave updated information on WHO Prequalification (PQ) procedures, focusing on the strategic priorities, including securing the supply base for priority vaccines for developing countries, facilitating access to quality products, improving efficiency of the prequalification procedure and to expanding portfolio for vaccine introduction. Related activities were conducted including the amendment of several WHO guidance documents [7–15], the implementation of expedited/facilitated registration procedure for prequalified vaccines in receiving countries, and two WHO workshops in China and India targeting at manufacturers with potential for PQ of priority vaccines. In 2013, an Internet based tool has been developed and hosted on WHO-server for online submission, processing and monitoring of registration applications.

She introduced the features of the revised procedure, notably, the Programmatic Suitability of Product Characteristics (PSPQ) committee, the streamlined prequalification procedure of 6 months for manufacturers in countries with eligible authorities, and the establishment of annual reporting systems (PQVARs). Finally, a customers' survey was made of PQ service design (PQ process) and service delivery. Still, there are concerns about overall time required for prequalification and process time inefficiencies (e.g. overall elapsed time, knowing when to expect a response). Manufacturers would like to see samples tested in parallel to the review of the file, while this may not be feasible to implement. In addition, there is a need for harmonization of expectations between different GMP auditors, categorization of deviations and of GMP code applied.

5. Panel discussion of Chief Executive Officers

This year the first open Chief Executive Officers (CEOs) Panel Discussion held at an annual general meeting was moderated by H. Dabas, from the Clinton Health Access Initiative (CHAI). CEOs from 9 DCVMN member companies discussed how to turning challenges into opportunities.

A. Homma from Biomanguinhos (Brazil) shared the success experiences in technology transfer from large multinationals to Brazilian manufacturers. He noted that the support from government is very important to facilitate negotiations with multinationals. The public immunization policy, the population acceptance and the market size are also components of success. A. Homma encouraged DCVMN members to intensify discussions and build up closer cooperation and technology transfer initiatives among Network members, which will leverage investments and better prepare emerging manufacturers to meet the supply challenges of developing countries.

C. Campa from Finlay (Cuba) noted that the five conditions for Finlay to turn challenges into opportunities included: the support from the local government, the high qualified human resources, the cooperation with other institutions inside and outside the country, confidence and loyalty to the solidarity principles of vaccination programmes across national borders, and existence of a robust system to carry out clinical trials.

S. Gao from Innovax (China) noted that the vaccine manufacturing quality management system is crucial to achieve WHO PQ, rather than the technology itself. He highlighted the recombinant vaccines based on a new *E. coli* expression system as an efficient vaccine technology platform. In addition to Hepatitis E, a new HPV vaccine has been developed based on the expression system. He emphasized that products with high cost-effectiveness will be very important for expanding immunization in developing countries. Finally, he expressed his interest in cooperation with other DCVMN members for technology transfer or development.

K. Ella, from Bharat Biotech (India) shared his vision on new vaccines' development. The attention to the specific health needs of the country and the strong will to be part of a solution to saving the lives of children are the key to succeed. With support from donors vaccine companies still have to face the challenge of how to keep the quality while keep affordable prices.

As illustrated by D. Dat, from Vabiotech (Vietnam), the manufacturers in Vietnam have been working closely with the government since the 1950s to eradicate polio and protect people from other infectious disease. However, applying for WHO PQ is a challenge that keeps the products of Vabiotech away from other populations in the world. Thus the company cooperated with other companies through technology transfer, for cholera vaccines for example, to make the product available globally.

M. Datla from Biological E (India) considers quality issues as daily business and great opportunities to introspect and improve the quality management system. She noted that the management of suppliers is also crucial to ensure the quality of final products. As for the partnership with international organizations such as GAVI, M. Datla noted that transparency in relationship and enough patience are very important approaches, especially to recognize the tangible added value of the partners.

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M. Makhoana from Biovac (South Africa) highlighted challenges for vaccine manufacturers in Africa, such as the lack of resources and specialized workforce. The company has to assess the epidemiologic data and balance the costs. In Africa, opinion leaders support vaccine manufacturers, and investors can expect the economic improvement in the future.

A. Muktadir from Incepta (Bangladesh), shared the story of how he started the business and illustrated the biggest challenges. One challenge comes from the PQ barrier because the local NRA is not considered fully functional. The simple motivation is to develop high quality vaccines for those people who need them. Dr. Muktadir expressed appreciation for the platform provided by DCVMN and expressed his interest in seeking partners for vaccine technology transfer to Bangladesh.

A. Poonawalla from Serum Institute of India, shared his successful business experience, and noted that patience and continuous investment are very important while fostering cooperation with international organizations, particularly to achieve PQ. Challenges such as to integrate the manufacturers, the donors and the NGOs into one common philosophy do exist. He gave two suggestions to DCVMN members: to establish strong R&D and quality systems and to register the products in as many countries as possible.

All CEOs agreed that DCVMN created a remarkable and vibrant platform to share knowledge and communicate solutions to emerging issues. It was concluded that entrepreneurial thinking is important to make changes happen and the Network community is serving a society where access to preventive vaccination will be fully met everywhere to assure supply of needed vaccines for future generations.

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 support to speakers or moderators to participate at this meeting.

Acknowledgements

We are grateful to all speakers and moderators, whose gracious participation and contributions made the conference possible. We are indebted to the US Human and Health Services (HHS) Department for the in-kind support of the registration website. We are grateful to the local organizing committee and to all volunteers who helped preparing and during the conference, especially Ms. Lan Huong for coordination of many logistic aspects of the conference. We thank Vabiotech and corporate partners for supporting DCVMN educational activities in 2013 with grants:Polyvac, Merck Millipore, Temptime, Bioengeneering, SGS, Alfa Wassermann, GEA, Bosch. This conference was partly supported by a grant of the Bill and Melinda Gates Foundation, Grant no. OPP1097005.

Appendix A.

Mahendra Suhardono (Biofarma, Indonesia), Akira Homma (Biomanguinhos, Brazil), Gutla V.J.A. Harshavardhan (Bharat Biotech, India), Morena Makhoana (Biovac, S.Africa), Mahima Datla (Biological E, India), Luciana Leite (Butantan, Brazil), Suresh Jadhav (Serum Institute of India), Yonglin Wu (CNBG, China), Yongzhong Gao (Innovax, China).

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[1] See Appendix A for collaboration details.

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Available online xxx