

Annual Report 2013



Connecting the World for a Cause

Table of Contents

Message from the President.....	6
Developing Countries Vaccine Manufacturers Are Saving Lives.....	7
Message from the Secretariat: Our challenge is improving vaccination for all people.....	8
Highlights 2013.....	10
News: DCVMN members are tackling regional diseases.....	11
Knowledge sharing.....	13
DCVMN convenes in Hanoi: Better vaccines for a healthier life.....	16
DCVMN voices : a CEOs' panel discussion.....	18
Governance statements.....	19
Financial statements.....	20
Acknowledgements.....	21
Nelson Rolihlahla Mandela.....	22

Executive Committee Members



Mr. Mahendra Suhardono
President
Bio Farma, Indonesia



Dr. G.V.J.A. Harshavardhan
Vice-President
Bharat Biotech International Limited
India



Dr. Akira Homma
Treasurer
Bio-Manguinhos (Fiocruz), Brazil



Dr. Yonglin Wu
China National Biotech Group., China



Dr. Luciana Cezar Cerqueira Leite
Instituto Butantan, Brazil



Dr. Morena Makhoana
The Biovac Institute, South Africa



Dr. Suresh S Jadhav
GAVI Board Alternate
Serum Institute of India, India



Dr. Steven Gao
Xiamen Innovax Biotech Co. Ltd., China



Ms. Mahima Datta
GAVI Board Representative
Biological E. Limited, India



Dr. Sonia R Pagliusi
Executive Secretary
DCVMN International

Message from the President

DCVMN had an excellent start with the support of 39 corporate members, spread over 15 countries and territories, and new partners joining our cause.

In 2013 Chengdu Biological Products Institute, Panacea Biotec, Biological E, and Serum Institute of India have achieved the prequalification of five additional vaccines for global supply: Japanese encephalitis, pentavalent (DTPHepB Hib), and bivalent & trivalent polio vaccines. Chengdu Biological Products Institute and Panacea Biotec have also upgraded to full members of the Network, which now comprises 10 members supplying WHO-prequalified vaccines to international agencies and national immunization programmes. Bio Farma has launched a Pentavalent vaccine in Indonesia, and Bharat Biotech launched typhoid conjugate and JE vaccines in India. We hope these achievements can serve as a positive trigger for other members to innovate continuously.

Our warmest gratitude goes to Vabiotech, all partners and sponsors, and the over 200 participants that made the 14th Annual General Meeting in Hanoi run smoothly in a vibrant atmosphere, with enhanced opportunities to foster international cooperation.

Along the year, more than 350 professionals have benefited from regional workshops hosted by members in Beijing, Mexico City, Hanoi, Rio, Buenos Aires, Hyderabad, Delhi and Bangkok, where experts from WHO, local governments, non-governmental organizations, industry and our members gathered to exchange knowledge and experiences on scientific and technical aspects of vaccines' quality. Together we gradually built an incredible global community of people who have entrepreneurial thinking to make changes happen. Our Network is serving to build a society where access to preventive vaccination will be fully met everywhere. The demand for local vaccines generates local employment bringing to full potential the multiple skills of everyone, for all levels of ability.

We shall welcome the upcoming challenges with confidence to assure supply of needed vaccines to future generations.

I believe we have an exciting journey ahead of us!



Mahendra Suhardono
DCVMN President

Developing Countries Vaccine Manufacturers Are Saving Lives

By TREVOR MUNDEL¹

President Global Health Programmes at Bill & Melinda Gates Foundation

October 18, 2013

The Vietnamese have a saying that, loosely translated, means ***adversity brings wisdom and gives birth to creativity***. It's an age-old proverb that rings true for me today, as I reflect on my recent time in Southeast Asia.

I traveled to Hanoi last week to attend the Developing Countries Vaccine Manufacturers Network's Annual Meeting (quite a mouthful, I realize). The DCVMN is a group of more than 38 vaccine manufacturers from 14 countries and territories, who work together to increase the quality of vaccines and access to them. Being from developing countries means they are at the most demanding of frontlines, facing the great task of immunizing the world's most under-served populations. They must be tight in their coordination, aggressive in their pursuit of a better product, and innovative in their navigation of regulatory pathways. I had a chance to meet with more than 10 companies and visit one of them – Bio Farma in Bandung, Indonesia.

As the Vietnamese saying goes, it is precisely the adversity faced by the DCVMN that has allowed this vast network to birth creativity and wisdom, and write one of the best global health stories of the last few years: more than two thirds of the world's children get their vaccines from DCVMs; more than 50% of GAVI's vaccine suppliers are DCVMs; and because of the work of the DCVMs, 370 million more children have been vaccinated since 2001 – with a 36% drop in cost in just the last two years. The DCVMs have also played a key role in contributing to global health's most powerful metric: **annual under-five mortality dropped to 6.6M in 2012**, down from more than three times that level in 1960.

Our job as a foundation is to continuously buoy our partners, and be advocates for regulatory, technological and financial support, to ensure that they can provide the best quality of vaccines at a cost that can be scaled.

Our commitment to the DCVMN is to remain a steadfast enabler of partnerships that can provide better prices and safer supplies. We are committed to scanning the world for innovations in vaccine development that we can share with DCVMs; to working with our partners in India and China to provide scientific and technical assistance that helps minimize regulatory delays that prevent drugs from reaching their targeted destinations; and to discovering new vaccines that are low-cost, single-dose and thermostable.

Many challenges remain. But the rewards, much like the great progress we've seen come out of the DCVMs so far, give much reason to be optimistic. There's another Vietnamese saying I learned this week: ***if you sharpen steel long enough, eventually you'll have needles***. While my translation is probably quite poor, it's the message holds many riches. I know that if we keep working diligently at overcoming the adversity before us, we will reach our goals of vaccinating every man, woman and child in Vietnam, the rest of the developing world, and beyond.

We are thankful to Dr. Mundel for his encouraging words!

DCVMN International Members

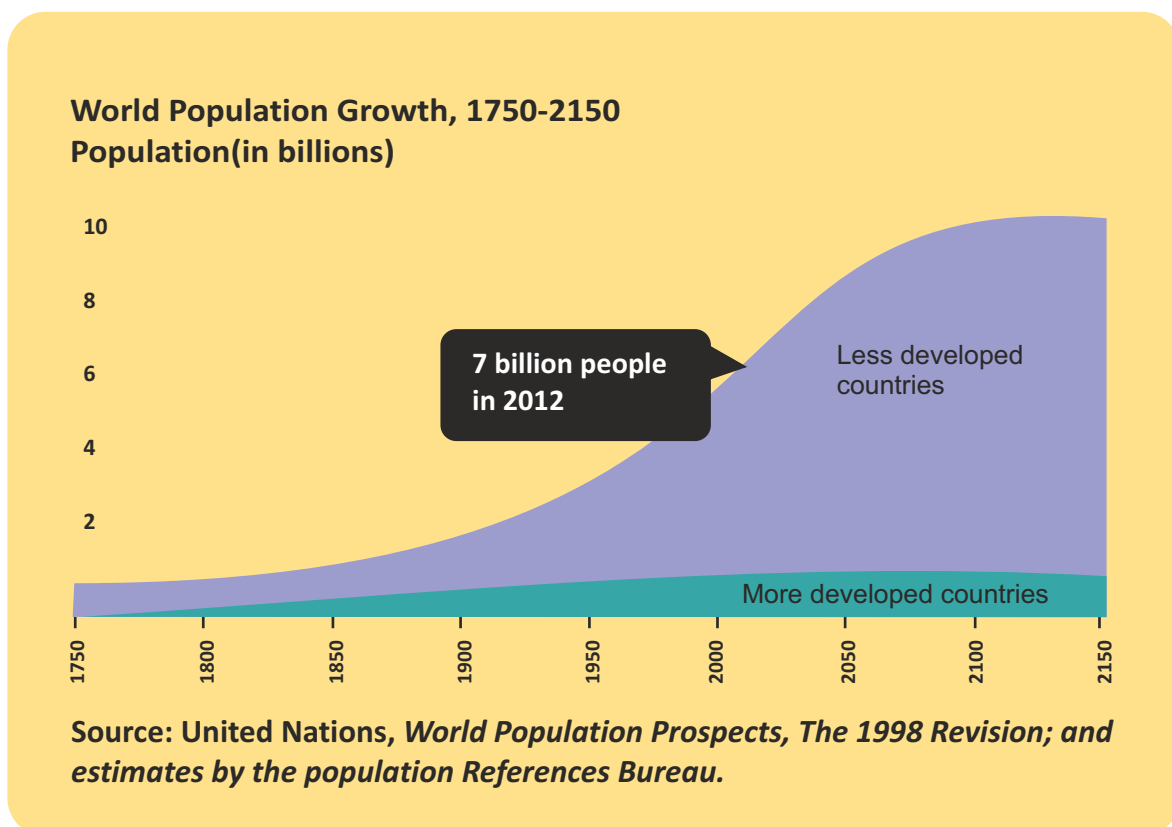


¹Article available at <http://www.impatientoptimists.org/Posts/2013/10/Developing-Country-Vaccine-Manufacturers-Are-Saving-Lives>

Message from the Secretariat: Our challenge is improving vaccination for all people

The Developing Countries Vaccine Manufacturers Network aims to protect people against infectious diseases by improving access to high-quality vaccines.

DCVMN is based on mutual trust and respect for different opinions among members and partners, and connects and informs vaccine producers worldwide, playing a strategic role in global vaccine supply and innovation. This essential role is favored by the great diversity and multi-cultural origin of members, reflecting a unique blend of public and private corporations and organizations well-placed to serve the populations where health needs are high. Cooperation between industry, governments, and not-for-profits allows us to take shared responsibility and move at the pace the world needs.



Our challenge is the fact that population growth rate over the last 50 years, as estimated by the United Nations, is higher in developing countries, while in contrast in more developed countries, populations remain stable. This imbalance in population growth seen over the last century may only intensify in the years to come.

²Population Bulletin: The World At 7 Billion <http://www.prb.org/pdf11/world-at-7-billion.pdf>
http://esa.un.org/wpp/unpp/panel_population.htm

DCVMN Annual Report 2013

Within ten more years, we may attain the eight billion people globally, as another billion people is likely to populate developing countries. Furthermore, while over 95% of children in industrialized countries are protected by vaccination against most common infections such as diphtheria, tetanus, pertussis, hepatitis B, measles, rubella, etc., only about 75% of children from developing countries have access to basic preventive vaccination, with pockets of even lower rates in certain regions.

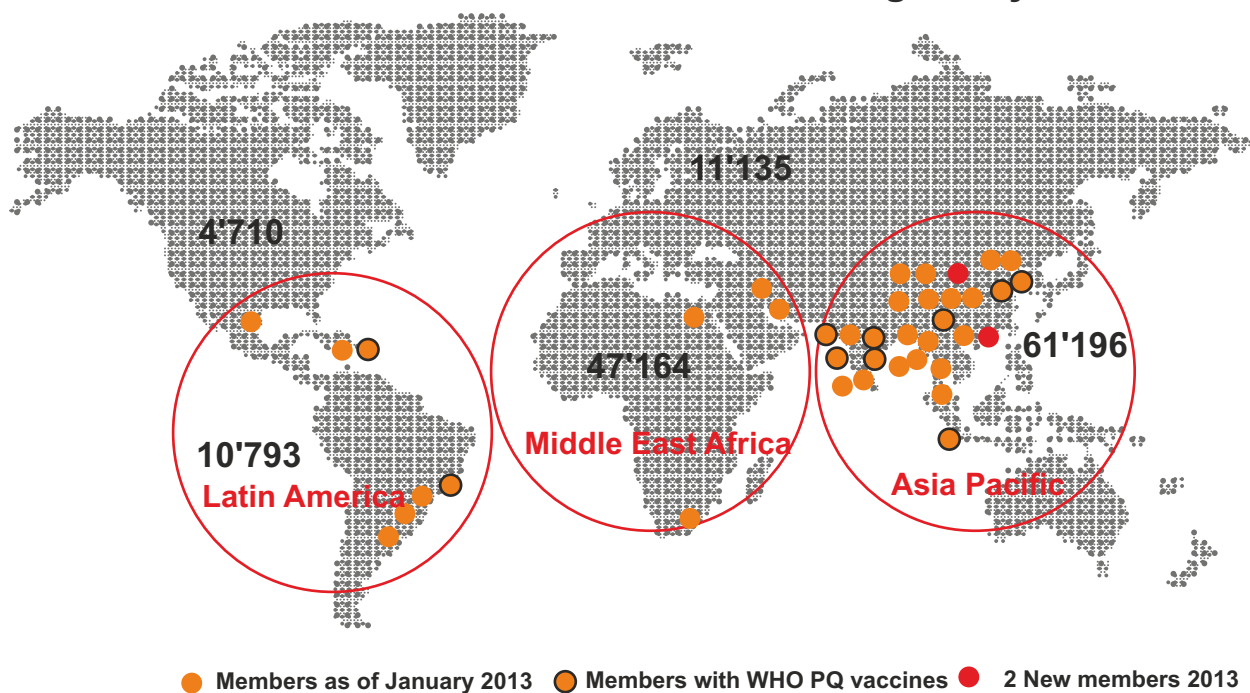
Recognizing that vaccines are a powerful tool in the prevention, control, elimination and eradication of infectious diseases, public and private vaccine manufacturers continue to expand their capacities, so the members of the Network can fill the gaps in providing sustainable supply of needed high-quality vaccines to developing countries' populations. Infectious diseases have no borders, and emerging epidemics in any country may represent a global threat.

We have invested time, resources and efforts to continue being a reliable, responsive and responsible partner to all vaccine manufacturers willing to take up this challenge together!

My work is a service to the global community and for future generations: that is something I am proud of.

Sonia Pagliusi
DCVMN Executive Secretary

DCVMN: 39 manufacturers from 15 Countries/ Territories and number of birth cohorts regionally

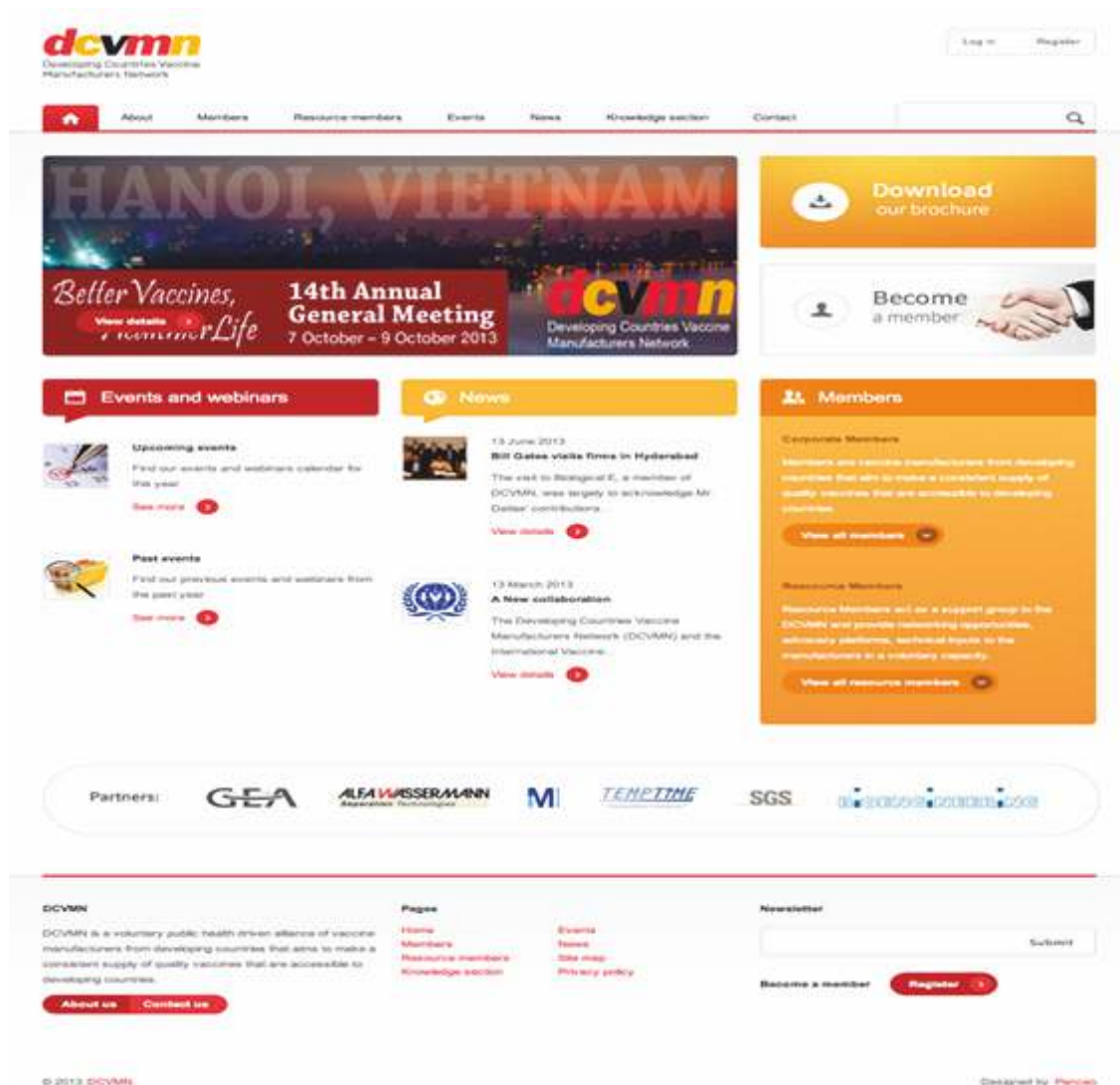


³<http://prorev.com/populate.htm>

Highlights 2013

A new website design

A new website design has been setup with new features aimed at improving communication, access to information, and transparency among members and the global health community. Values, governance, members and activities are outlined in the various sections of the website. Notably, activities organized by DCVMN and also by partner organizations are shared on a calendar of events.



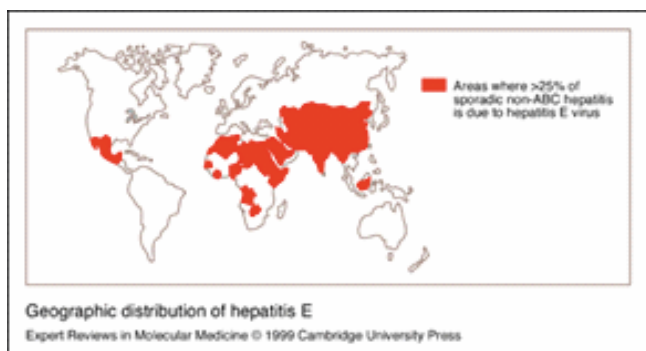
News: DCVMN members are tackling regional diseases

Responding to pressing regional and global health threats, several Network corporate members moved towards innovative approaches to improve access to needed vaccines. Following the success of the meningitis A vaccine, created specifically to control epidemics in African meningitis belt countries, other regional diseases are being tackled by innovative vaccines.

January 29th, 2013: Xiamen Innovax starts distribution of world's first Hepatitis E vaccine

The HepE vaccine was approved for production in December 2011 and hit the Chinese market in late 2012 after a 14 year odyssey of research, development and clinical trials. The company is now working with the government to offer the vaccine to high-risk groups of populations, and is also cooperating with international organizations to distribute it to other countries.

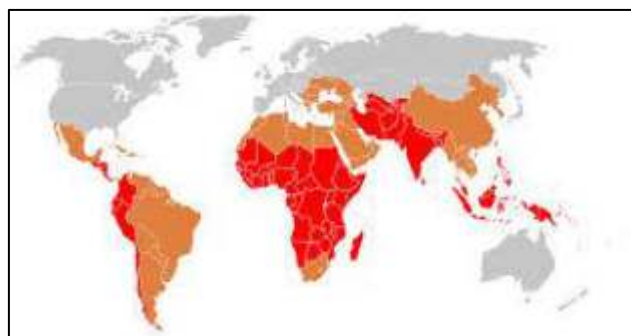
The water-borne hepatitis E virus spreads through tainted water and food. The World Health Organization estimates that 20 million people around the world are infected by the virus each year. In China, hepatitis E is now the most common type of hepatitis infecting adults. Hopefully, the vaccine will curb the spread of Hepatitis E in China, Southeast Asia and the rest of the world.



Source: Xiamen HiTech FrontLine,
http://202.101.105.165/pub/2010english/Front_Line/201302/t20130209_614650.html

August 26th, 2013: Bharat Biotech announced the launch of the first clinically proven typhoid conjugate vaccine.

Bharat Biotech's Typhoid conjugated vaccine is a fourth generation vaccine, providing long term protection against disease to adults and infants six months and older. Currently available Typhoid vaccines fall short in two major characteristics, namely long term protection and protection for children below two years of age, the population that needs it the most.



Typhoid fever is a life threatening illness caused by the bacterium *Salmonella typhi*, which is transmitted through contaminated food or drink water. Symptoms include high fever, malaise, headache, constipation, diarrhea, etc. It causes between 250,000 to 600,000 deaths and 20 million illnesses per year, affecting mostly school-age children. While typhoid fever can be cured by antibiotics, resistance to anti-microbials is widespread along with poor diagnostics, prevention of typhoid fever is better than the cure.

Excerpt taken from: **The Hindu Business Line**,
<http://www.thehindubusinessline.com/companies/bharat-biotech-launches-typhoid-vaccine-for-longterm-protection/article5060932.ece>

July 12th, October 4th, and October 9th, 2013: Newly accessible vaccines against Japanese Encephalitis make it easier to protect more children in developing countries.



Vaccines manufactured in China and India are more affordable and Japanese encephalitis vaccines have received WHO pre-qualification for United Nations

procuring agencies: on July 12th, from Biological E, and on October 9th, from Chengdu Biological Products Institute. Japanese encephalitis, a mosquito-borne flavivirus infection, is a severe disease that involves inflammation of the brain. It is a major public health problem and is endemic with seasonal distribution in parts of China, the Russian Federation's south-east, and South-East Asia.

As there is no specific treatment for Japanese encephalitis, the disease is preventable by effective vaccines, and the newly available vaccines are now accessible to the world. A further JE vaccine was launched in India by Bharat Biotech on October 4th, and is yet to get WHO pre-qualification.

Source: World News,
http://article.wn.com/view/2013/10/09/Encephalitis_Vaccin_for_Children_in_Developing_Countries/#/related_news

November 18th, 2013: Brazil to produce measles and rubella vaccine for poor countries



(Source: Reuters,
<http://www.reuters.com/article/2013/10/28/us-brazil-measles-idUSBRE99R0IQ20131028>)

Brazilian health minister announced the vaccine plan at a medical science conference that the Gates Foundation coorganized in Rio de Janeiro. Brazil is following other leading emerging nations such as China and India in investing in biomedical technology to supply vaccines and medicines to developing countries at lower costs of urgently needed vaccines. Measles kills 158,000 people a year in the world, mostly children under the age of five. Rubella, a contagious viral disease with symptoms like mild measles, can cause serious consequences to pregnant women and their babies.

Knowledge sharing



Image credit: <http://www.empathica.com/resource/r2-managing-the-guest-experience-the-importance-of-sharing-knowledge-across-locations/>

In 2013 DCVMN launched a new initiative to support continuing education programmes among professionals of the industry between developed and developing countries. A memorandum of understanding was signed with the International Vaccine Institute (IVI), to improve professional competencies by serving as a hub to intensify training in how to scale up of vaccine manufacturing, particularly in the Asia-Pacific region.

A series of regional workshops for continuing education on Quality Management Systems and New Technologies were organized over 2013 and hosted by members in major cities, bringing together over 360 industry professionals on a regional basis.

Date	DCVMN QMS workshops title	Site	Number of Participants ¹	Host
May 10 2013	Post licensure variations and changes to vaccines	Beijing	48	CNBG
July 10-11 2013	Sharing experiences in regulatory pathways for PQ of OPV	Mexico City	50	Birmex
July 20 2013	Cell banks characterization	Beijing	50	Minhai, Sinovac, & CNBG
October 10-11 2013	Key performance indicators	Hanoi	25	Vabiotech & PATH
October 24-25 2013	Approaches to risk assessment	Rio	70	Bio-Manguinhos
October 29-30 2013	Introduction to PQ	B. Aires	18	Sinergium & Anlis
November 13 2013	Cell banks characterization and stability testing	Hyderabad	37	Bharat Biotech
November 15 2013	WHO post licensure variations and changes to vaccines	Delhi	25	Panacea Biotec
November 19 2013	Biosafety assessment of vaccines for global marketing	Bangkok	45	GPO
Total			368	

⁴According to our records

DCVMN Annual Report 2013



Dr. E. Martinez, Workshop in Mexico City



QMS workshop participants, Beijing



PATH KPI workshop participants, Hanoi



Biosafety workshop faculty, Bangkok

DCVMN Annual Report 2013

A series of Webinars continues to connect members with outstanding global experts to discuss current trends in quality, technical, access, policy, regulatory and biosafety aspects of vaccines. (see table below). This initiative is cordially supported by SGS.



Image Credit: <http://www.stevenbarnes.ca/limited-time-special-invite-webinar/>

Date	Subject	Speaker	Registered participants
25.08.2012	Quality compliance challenges and current trends for Biopharmaceutical Products	Fernanda Sanchez-SGS	68
25.09.2012	Procedure for Expedited Review of imported prequalified vaccines for use in national immunization programmes	Anil Kumar Chawala-WHO	39
29.11.2012	Quality from all Angles ICH Q8, Q9, Q10	George A. Robertson-PATH	57
31.01.2013	The Consistency approach in lot release of established vaccines	Coenraad Hendriksen-NVI	43
06.03.2013	Biosafety considerations for Cell Based Viral Vaccines	Margaret Temple-SGS	35
14.05.2013	GAVI Alliance Overview & Vaccine Investment Strategy	Judith Kallenberg-GAVI	24
27.06.2013	Ultracentrifugation: downstream processing tool for large scale viral vaccines	Sandra Merino Alfa Wassermann	29
19.09.2013	The Sabin IPV Technology Transfer Project	Hamidi INTRAVACC	15
23.10.2013	Aseptic Vaccine Process Validation Sterile Filter Focus	Michael Payne-Millipore	63
05.12.2013	Immunization supply chain: key challenges impacting national immunization programmes	Diana changblanc & Patrick Lydon – WHO	25

**some participants reported to be all together in a meeting room and attend under one registered name*

The recorded sessions are available to all members on DCVMN website for consultation and replay.

DCVMN convenes in Hanoi: Better vaccines for a healthier life

Under the auspices of Vabiotech, the Developing Countries Vaccine Manufacturers Network (DCVMN) brought together over 200 senior representatives of governmental and non-governmental global health organizations, as well as corporate executives of emerging vaccine manufacturers from 26 countries, gathered for two days of tailored lectures, Q&A sessions, panel discussion and networking opportunities, followed by a vaccine-technology symposium and visit to manufacturing facilities in Hanoi, Vietnam.

The honorable Vice-Minister of Health of Vietnam commended the speakers and participants at 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 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 the spread of measles and hepatitis B. Speaking at the conference, the honorable Vice-Minister Nguyen Thanh Long said that vaccines have played an important role in reducing the mortality rate from infectious diseases.



Dr. Mundel



Prof. Thuvan

DCVMN Annual Report 2013



Delegates



M. Malhame



M. Suhardono and G. Harshavardhan



Korean delegates



*S. Thirapakpoomanunt from Thailand,
and other delegates*

DCVMN voices: a CEOs' panel discussion

The first open Chief Executive Officers (CEOs) Panel Discussion, moderated by H. Dabas, from the Clinton Health Access Initiative (CHAI), was held at an annual general meeting this year. CEOs from nine DCVMN member companies had a plenary discussion on how they are turning challenges into opportunities.



From left to right : H.Dabas, A.Poonawala, M.Datla, M.Makhoana, A.Muktadir



From left to right: D.Dat, K.Ella, C.Campa, A.Homma, Y.Gao

Governance statements

The Executive Committee receives, reviews, and approves regular reports from the Secretariat pertaining to the operations. Monthly reports are presented verbally at teleconferences, and quarterly written reports are presented to the Executive Committee at the end of each quarter.

Meetings and teleconferences (TC) are structured with pre-set agenda items and relevant documents are circulated to ensure the information is available when necessary to facilitate informed decision making. In addition, DCVMN representatives appointed as senior advisers to the Executive Committee serve at the GAVI board.

All Executive Committee members act on a voluntary, non-remunerated basis.

In 2013 there were 10 Executive Committee teleconferences on: January 8th, February 6th, March 7th, April 2nd, May 21st, June 18th, July 4th, September 10th, November 15th, and December 16th, and one face-to-face EC meeting held on October 6th. Participation of executive committee members is shown in the table below. GAVI Alliance Board representatives also attended two GAVI Board meetings within the calendar year. At the final quarter of the calendar/financial year the network's activities and interim financial statements were presented by the executive committee to the assembly of members, on October 6th. The proposed 2014 activities and budget were approved by the assembly.

President	Mr. Mahendra Suhardono	Bio Farma	6/11
Vice-President	Dr. Harshavardhan	Bharat Biotech International	9/11
Treasurer	Dr. Akira Homma	Bio-Manguinhos	5/11
Member	Dr. Morena Makhoana	The Biovac Insitute	5/11
Member	Dr. Yonling Wu	CNBG - Sinopharm	6/11
Member	Dr. Luciana Leite	Instituto Butantan	6/11
Member	Mr. Steven Gao	Xiamen Innovax	7/11
Gavi Board Member (non-voting)	Ms. Mahima Datla	Biological E	1/11
Gavi board alternate*& EC Senior Adviser (non-voting)	Dr. Suresh Jadhav	Serum Institute of India	10/11
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	11/11

*Until June 2013

Financial statements

Over the year 2013, DCVMN associative income has increased by 64% from 223 thousand USD to nearly 375 thousand USD, without any increase in membership fees and marginal increase in number of members (from 37 to 39). This was mainly due to fundraising activities and private donations. DCVMN is moving towards a diversified resources base, similar to many other international associations, to achieve a sustainable and balanced operations model. DCVMN international handles no cash, and all income and disbursements are subject to two signatures including treasurer, corresponding to bank transactions on records. Of note, in 2013 the dollar devaluation compared to Swiss francs has contributed to foreign exchange loss that reflects the value of the dollar on 31st December 2013 as compared to the average exchange rate of the dollar over the whole year.

DCVMN International Statement of Income and Expenditure for the year ended on 31st December

Year	2013 ¹		2012 ²	
INCOME	CHF	USD	CHF	USD
Membership contributions	204'048.00	218'000.00	202'060.30	221'000.00
Private donations	105'077.90	112'262.71	0.00	0.00
Annual meeting grant	32'498.86	34'721.00	0.00	0.00
Annual meeting participants contributions	7'570.21	8087.83	0.00	0.00
Extraordinary income, interest & exchange gain	34.10	36.52	2'646.15	2'894.17
Total Income	349'229.07	373'108.06	204'706.45	223'894.17
EXPENDITURE				
Wages & social charges	86'708.85	92'637.46	89'778.55	98'193.74
Insurance, LPP & office related expenses	11'046.17	11'801.47	10'251.55	11'121.45
Professional fees	6084.00	6499.99	234.00	255.93
Website fees	5'000.00	5'341.88	0.00	0.00
Annual meeting	39'763.16	42'482.01	0.00	0.00
Foreign Exchange loss	15'553.09	17'556.64	0.00	0.00
Bank charges & tax on capital	2036.22	2178.04	755.64	826.42
Total expenditures	166'191.56	178'497.49	101'019.74	110'488.54
BALANCE	183'037.51	194'610.57	103'696.71	113'405.63

⁵The non-audited financial statement was controlled by Multi-Fiduciaire Services, Geneva. (www.multigeneve.ch)

⁶Annual average exchange rate at 0.9360 dollar for 1 CHF

⁷Annual average exchange rate at 0.9143 dollar for 1 CHF

Acknowledgements

To facilitate knowledge sharing and intensifying training opportunities for a skilled industry workforce, the annual meeting and regional workshops held in developing countries were organized together with partners. We are grateful to corporate partners (see below) for their interest, collaborative spirit and support helping foster manufacturing excellence for the benefit of all people.

We thank Vabiotech and other partners for hosting and supporting the annual meeting, and the Bill and Melinda Gates Foundation for a conference Grant (grant no. OPP1097005).

We are also indebted to the US Human and Health Services (HHS) Department, for the in-kind support for registration for the annual meeting.



Nelson Rolihlahla Mandela

18 July 1918 – 05 December 2013



“Giving children a healthy start in life, no matter where they are born or the circumstances of their birth, is the moral obligation of every one of us. It is heartbreaking to think that three million children die each year from diseases that we can prevent.”

Address by Nelson Mandela at Vaccine Conference, April 2002

The world will no longer hear the great freedom fighter's forgiving voice, but he left us a huge legacy. We are forever grateful!

DCVMN members





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