



Developing Countries Vaccine
Manufacturers Network

A network diagram is overlaid on the blue background, consisting of white dots (nodes) connected by thin white lines. The nodes are arranged in a way that suggests a global or interconnected network, with some nodes having multiple connections to other nodes.

2018 Annual Report

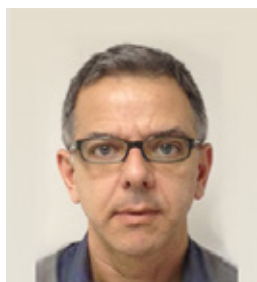
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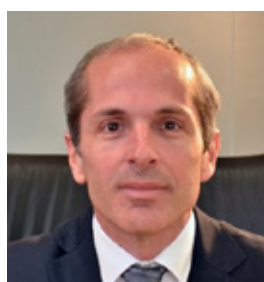
EXECUTIVE COMMITTEE MEMBERS



Ms. Mahima Datla
President
Biological E. Limited, India



Dr. Alexander Roberto Precioso
Vice President
Instituto Fundação Butantan, Brazil



Mr. Fernando Lobos
Treasurer
Sinergium Biotech, Argentina



Mr. Sai D Prasad
Bharat Biotech International Limited, India



Ms. Lingjiang Yang
China National Biotech Group, China



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



Mr. Patrick Tippoo
The Biovac Institute, South Africa



Dr. Sonia R Pagliusi
Executive Secretary
DCVMN International

Message from the President

Dear Members, Partners and Friends,

On behalf of the Network, I would like to extend our thanks for your participation in DCVMN which adds immense value towards learning and finding an important common platform for discussing challenges that we face today.

To update you about our membership, in 2018 three new corporate members joined the Network bringing the total DCVMN membership to 53, the highest ever. We welcome the new members, Pasteur Institute of India, Nanolek, and Korea Vaccine, to the Network and look forward to a mutually beneficial association over the coming years.

This year, five members of our Network received WHO prequalification (PQ) for six products. Sinovac received PQ for HepA vaccine, BioE for JE vaccine, Beijing Bio for bOPV, SII for Rotavirus, and Bharat Biotech for TCV and Rotavirus. My heartiest congratulations to these companies.

In 2018 our Network turned 18! Let's take a step back and look at the journey so far. The Network was started in 2000 with less than 10 members. At the time, the Network's mandate was mainly to provide members with training to ensure they were up-to-date on international regulatory and quality requirements. Together we have evolved into a 53-member strong organization providing a platform for meaningful discussions on immunization related issues and acting as an active voice in relevant fora. Towards this, we have conducted a strategic exercise to understand the focus areas that



our members consider important for the Network to address in the future.

Today we are also working on novel technologies in terms of development, analysis and delivery. Novel funding mechanisms are available and there is increasing commitment from governments, regulatory bodies and other immunization stakeholders. New suppliers have joined the highly specialized vaccine industry in recent decades. The environment couldn't have been more conducive. It is now important for manufacturers to take on the largest share of the responsibility, and it's a moral obligation for us to create and provide products as per the required volumes and specifications for developing countries.

Sincerely,

Mahima Datla
DCVMN President

Bill Gates: “looking forward to the partnerships we can have over the next decade”



Photo Credit: DCVMN International. Bill Gates interviewed for the DCVMN International Annual General Meeting 2018.

30th October 2018 - Vaccine manufacturers from emerging countries convened in Kunming, China, to recognize vaccine industry partnerships that help advance global health initiatives.

Bill Gates was interviewed (by recorded video), reflecting on achievements of the first decade of vaccines. Annual child mortality decreased from over 11 million in the 1990s to around 5 million today. “In saving children’s lives there is nothing as phenomenal as vaccines and the vaccine industry”, said Bill Gates.

In this context, ensuring simple procurement practices and guaranteed supply, avoiding fragmentation, working on policies and providing technical advice to countries should help drive global and

regional vaccine uptake, as well as stockpiles, increasing access to vaccines for everyone. In general, some redundancy in manufacturing is needed to ensure economies of scale and sustainable global supply capacity if a plant goes offline.

He commended DCVMN companies for exploring state-of-the-art manufacturing technologies and stated that BMGF is committed to a strong dialogue and willing to share risks that make a difference to global health. Bill Gates concluded: “we are looking forward to the partnerships we can have over the next decade”.

More information at <https://www.dcvmn.org/Bill-Gates-looking-forward-to-the-partnerships-we-can-have-over-the-next-decade>

DCVMN engaged in open dialogue with ICDRA about challenges and opportunities for alignment of procedures for vaccine registration



Photo credit: DCVMN International

4th September 2018 - The organizers of the International Conference of Drug Regulatory Authorities (ICDRA) invited the DCVMN regulatory expert working group to join the pre-ICDRA session on “Enabling access to innovative medical products in resource-limited settings” and present the recently published study, conducted in collaboration with IFPMA, on the challenges for the registration of vaccines in emerging countries.

A DCVMN representative, I. Susanti from Biofarma, delivered the lecture and participated in a panel discussion, elaborating on opportunities and future options for regulatory convergence in addressing the challenges, while respecting regulatory requirements.

The conferences, established by WHO as a platform to develop international consensus, promote exchange of information and collaborative approaches to regulatory issues of common concern. DCVMN commends ICDRA for serving as an important instrument for WHO and drug regulatory authorities in their efforts to harmonize regulation of medicinal products.

More information at <https://www.dcvmn.org/DCVMN-engaged-in-open-dialogue-with-ICDRA-about-challenges-and-opportunities>

DCVMN members' engagement in vaccines' development and supply



Biovac awarded manufacturing license for parenteral products

Cape Town, 18th April 2018 – The Biovac Institute was awarded a manufacturing license by a South African regulator, taking it one step closer to realizing the government's goal of producing its own vaccines.

Biovac, as a public-private partnership, formed in 2000, aims to revitalize the state's human vaccine manufacturing capacity, by sourcing and distributing vaccines for the national programme for immunizing infants and children. It also provides vaccines to the private sector.

In January, Biovac was notified by the South African Medicines Control Council that the Pinelands, Cape Town facility, had been approved for the manufacturing of vaccines and other parenterals, said the CEO Morena Makhoana.

More information at:

<https://www.businesslive.co.za/bd/companies/healthcare/2018-04-18-regulator-gives-bio-vac-green-light-to-manufacture-vaccines/>



Launch of first JE vaccine immunization campaign in Indonesia

On 1st March 2018, the Launching Ceremony of the First Immunization Campaign for Japanese Encephalitis was held in Indonesia. Representatives from Chengdu Institute of Sinopharm-CN BG participated in the ceremony at the invitation of Indonesian Ministry of Health.

The Minister of Health of Indonesia, expressed his gratitude to Sinopharm International and Chengdu Institute, the supplier and the manufacturer of JE vaccines, for their efficient supply. Thereafter, students from SMPN 1 Tabanan Middle School were vaccinated.

In 2017, the first supply of JE vaccines of more than 1.1 million doses were exported to Indonesia to be used for an immunization campaign among children aged 9 months to 15 years in Bali Province - the area most affected by encephalitis B - to contain the spread of the disease. It is expected that the JE immunization campaign will be expanded to include more areas.

Sinopharm International will continue to provide JE vaccines of international standard to Indonesia and the entire Asian JE endemic area in cooperation with Chengdu Institute of Sinopharm CNBG and make efforts for disease control in related areas.

More information at: <http://www.sinopharm.com/en/s/1395-4173-35286.html>



WHO prequalifies a novel live-attenuated Rotavirus vaccine from Bharat Biotech

Hyderabad, 5th January 2018 – ROTAVAC® has been under development since the year 2000 with investments of around USD 200 million and dedicated manufacturing infrastructure. The Genome Valley facility has an installed manufacturing capacity of up to 200 million doses per year, to meet global demand.

“We are honored and delighted to become the first rotavirus vaccine from the developing world and India to be WHO Prequalified. The true impact of vaccines can be seen when vaccinations are carried out in affected populations. The Government of India has given a big boost by making ROTAVAC® available to millions in India already.» said Krishna Ella, Chairman and Managing Director of Bharat Biotech. Bharat Biotech received the National Technology Award for 2018 from the Technology Development Board, Government of India, for successfully developing this vaccine.

More information at:

https://www.bharatbiotech.com/images/press/Bharat_Biotech_2018_pressrelease2.pdf

https://www.bharatbiotech.com/images/press/Bharat_Biotech_2018_pressrelease3.pdf



New heat-stable oral Rotavirus vaccine prequalified by WHO

Pune, 25th September 2018 – The World Health Organization prequalified Rotasil, an oral rotavirus vaccine produced by Serum Institute of India. Rotasil is the first Rotavirus vaccine with heat stable characteristics, which makes it particularly suitable for use in low-income countries, where weak infrastructure and frequent lack of electricity make refrigeration very difficult.

Rotavirus is responsible for about 37% of deaths from diarrhoea among children younger than 5 years of age worldwide, with a disproportionate effect in parts of Africa and Asia. Because the disease is so widespread and serious, rotavirus vaccines should be included in all national immunization programmes and considered a priority, particularly in countries with high associated death rates, such as in south and south-eastern Asia and Africa.

The addition of Rotasil to the WHO list of prequalified vaccines will help expand the global supply of rotavirus vaccines, increasing countries' options to address the disease. It is also possible that it will reduce the price of available quality-assured vaccines through greater competition.

More information at:

<https://www.who.int/medicines/news/2018/prequalified-new-rotavirus-vaccine/en/>



Japanese Encephalitis vaccines for infants prequalified by WHO

Hyderabad, 2nd October 2018 – WHO prequalified the Japanese Encephalitis vaccine from Hyderabad-based biopharmaceutical company Biological E (BioE) for global use.

WHO prequalification is a key step for distribution of the vaccine in developed countries. BioE developed the vaccine based on the technology of Valneva SE, a French biotech company. The two companies entered into a partnership in 2005 and the vaccine is presently marketed in India under the trade name JEEV.

“It is an important achievement for the vaccines community as our vaccine’s prequalification is well in time to support GAVI’s introducing the JE vaccine in many developing countries,” said BioE Managing Director, Mahima Datla.

GAVI, the Vaccine Alliance, is a public-private partnership to save children’s lives and protect people’s health by increasing access to immunization in poor countries.

More information at:
<http://biologicale.com/pdf/JVEE.pdf>



Bivalent OPV prequalified by WHO to help end polio globally

New Delhi, 7th December 2018 – In line with efforts to end poliomyelitis and ensure uninterrupted supply of vaccines, WHO prequalified a bivalent oral polio vaccine, from Panacea Biotec.

As recently as 30 years ago, wild poliovirus paralyzed more than 350 000 children in more than 125 countries every year. Now, less than 30 reported cases were reported in 2018 in just two countries – Afghanistan and Pakistan – and the world stands on the cusp of an unprecedented public health success: the global eradication of a human disease for the second time in history.

The aim of teams on the ground in Afghanistan and Pakistan is very clear: find and vaccinate every child before the virus reaches them.

Until poliovirus transmission is interrupted in these countries, all countries remain at risk of importation of polio, especially vulnerable countries with weak public health and immunization services and travel or trade links to endemic countries.

More information at:
<http://polioeradication.org/> or <https://www.who.int/news-room/feature-stories/detail/pakistan-and-afghanistan-the-final-wild-poliovirus-bastion>

Expert webinar series: real time engagement



DCVMN held a series of 11 webinars throughout the year 2018. Subject matter experts were invited to share their views and knowledge with our members, taking advantage of the power of Webex online communication technology.

Date	Topic	Presenter (affiliation)	Number of connections*
15 February	Pharmacovigilance Monitoring System Requirements	V. Thuja (Aris Global)	14
13 March	Humidity Control in Vaccine Manufacturing - A GMP Perspective.	M. Ginty (Munters)	50
12 April	The Future Vaccine Manufacturing Hub led by Imperial College, London.	R. Shattock (IFVMH)	15
24 May	Unleashing the power of rabies vaccines. «Reaching zero by 2030».	B. Abela-Ridder & A. Ives (WHO)	12
21 June	How to inspect glass containers before filling.	A. Pettenuzzo (Stevanato)	23
12 July	VVM overview - Temperature Intelligence Solutions	M. Rush (Temptime)	N/A
13 September	Biosecurity for Vaccine Producers: Dual Use Equipment of Concern	L. Winona & V. Halkjaer (Sandia Labs)	N/A
08 October	Asia's Vaccine Market: Opportunity, Risks and A Plausible Future.	J. Uzonwanne (IQVIA)	34
30 October	Visual inspection technology for filled vaccines	B. Damien (Univercells)	10
15 November	Technologies for Vaccine Delivery and Thermostabilization	C. Rongjun & J. Hallett (FVMH)	25
13 December	Improved design and operation of vaccine manufacturing through process modelling.	N. Shah & Z. Kis (FVMH)	26

Table 1. Summary of DCVMN hosted webinars 2018.

* some attendees connected as groups, hence it is estimated that the number of attendees is at least double.

Teach to Reach

Training for developing countries' vaccine industry professionals



Shanghai workshop participants, March 2018.

In 2018, together with its partners, DCVMN organized a series of professional training workshops, focused on topics related to Quality Management Systems, as well as other cross-cutting subjects of common interest to vaccine manufacturers. The workshops bring international experts to provide updates to professionals from DCVMN corporate members on current GxP and technology trends for developing, producing and supplying high-quality vaccines. In total, 228 participants attended regional workshops in 2018, maintaining a balanced gender participation (44% female and 52% male; 4% were unidentified), from 25 companies and 12 countries. The location, topic and attendance of regional workshops are shown in the table below.

In 2018, participants were asked to complete an e-learning course in preparation for the workshops, which improved the face-to-face interactions. Participants were encouraged to disseminate the knowledge acquired by teaching colleagues on how to follow the online courses for self-learning. This way a larger number of professionals will have access to the knowledge following every workshop, for those unable to join the workshops in person. In 2018, we observed that nearly 1 400 people enrolled in DCVMN E-learning courses and approximately 600 achieved certificates, a threefold increase compared to 350 and 170, respectively, in 2017 (see E-learning section below).

Date	Location	Topic	N° of participants
11 - 12 January 2018	Geneva, Switzerland	CTD Expert Working Group Workshop	18
5 - 8 February 2018	Singapore, Singapore	Biosafety compliance, process optimization and clinical studies	40
19 - 22 March 2018	Shanghai, China	Vaccine thermo-stability, bioprocess and registration dossiers	61
7 - 10 May 2018	Hyderabad, India	Optimization of vaccines' manufacturing, containers and testing for global supply	45
18 - 20 June 2018	Rio de Janeiro, Brazil	Data Integrity Systems and CTDs	47
1 - 3 October 2018	Dhaka, Bangladesh	Biorisk management	17
TOTAL			228

Table 2. Number of participants at DCVMN workshops in 2018, excluding speakers and secretariat staff. These professional education efforts were partially supported by a grant from the Bill and Melinda Gates Foundation (Grant no. OPP1113279).



Working group session, March 2018.



Hyderabad workshop participants, April 2018.



June 2018 - Participants at workshop in Brazil.



Participants of “Data Integrity” session in Brazil, June 2018.

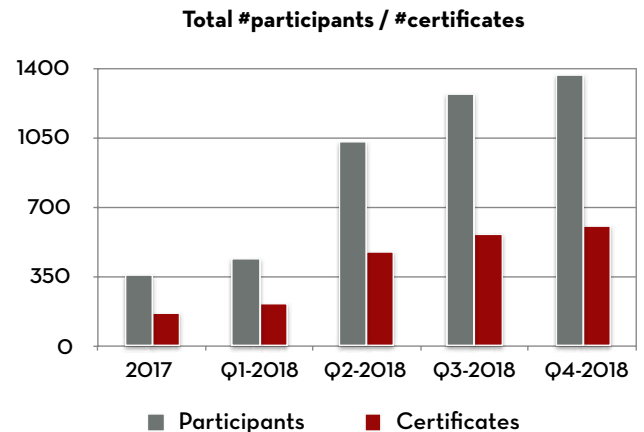


Dhaka workshop participants, October 2018.

Everybody matters: E-learning for all

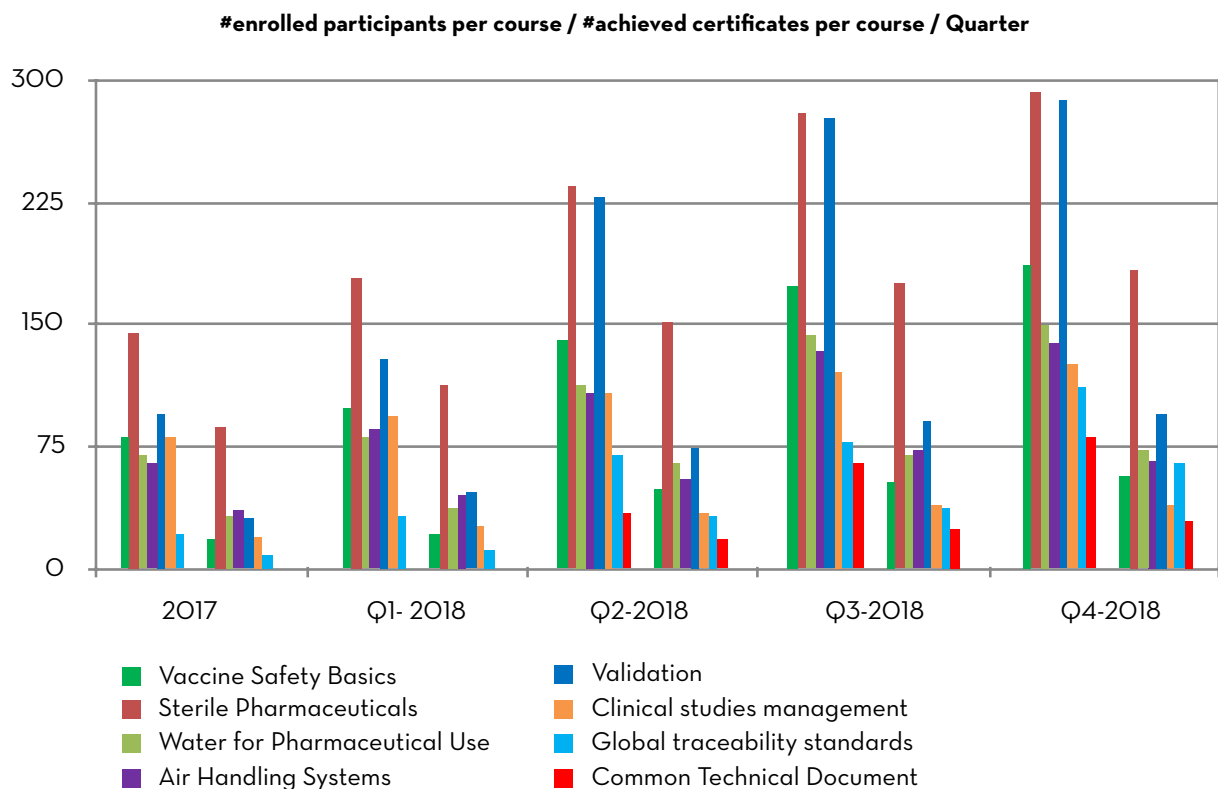
The DCVMN E-learning platform, launched in December 2016, allows professionals to freely access online learning materials on specific topics relevant to vaccine development, manufacturing and supply. Courses are based on self-tutorials, and organized in three categories: Engineering & Process, Clinical Monitoring & Regulatory Affairs, and Supply Chain & Distribution. Courses are freely accessible through our Website; cf. <https://moodle.dcvmn.net>. After completing each course, a self-evaluation tool with automatic correction enables users to test the acquired knowledge on the respective topic; a customized certificate can be downloaded for each completed course, if users score 80% or higher on the test.

In 2018, 1'369 participants enrolled and followed E-courses (grey columns), and 605 have achieved course certificates (red columns). In total, eight E-learning-modules were available online, as listed below, for professionals to choose and follow volun-



tarily. The first set of columns displays the number of enrolled participants per course; the second set of columns displays the number of achieved certificates per course. More E-learning courses will be added in the coming years and corporate partners are invited to contribute.

More information available at <https://moodle.dcvmn.net>



The art of partnerships

DCVMN Annual Meeting, 29-31 October, Kunming, China



Bill Gates, addressed the delegates by recorded video, reflecting on achievements of the first decade of vaccines. He commended DCVMN companies for incorporating new “state of the art” manufacturing technologies, and stated his commitment to a strong dialogue, and willingness to share risks that can make a difference to global health, reducing morbidity and mortality from infectious diseases.



Bill Gates addressed the audience, by recorded video, at the opening session, 30th October 2018.

For its 19th Annual General Meeting in Kunming, leading representatives of the Chinese Health Authorities, World Health Organization, UNICEF and other global health stakeholders gathered to foster innovation through open dialogue with vaccine manufacturers.

Partnerships for vaccines require collective efforts that were discussed among experts in open panel discussions around the following main topics:

- Partnerships
- Financing for Vaccines
- R&D Innovation
- Regulatory Convergence
- Vaccines Procurement
- Innovative Technologies
- Futures Vaccines
- New Quality Standards

Opening Session and Welcome speech



Opening by DCVMN President, M. Datla, and Welcoming remarks by Executive President IMBCAMS (??).



Partnerships open panel discussion, from left to right: J. Chu (CHAI), M. Zuma (BioManguinhos), S. Davies (PATH), M. Simao (WHO), P. Tippoo (Biovac), H. Iyer (BMGF).

Views and opinions

from CEOs and leading experts around the world...



...about financing, R&D, technology innovation and future vaccines.







Governance statements

The Executive Committee (EC) reviews, advises and approves, on behalf of members, the day-to-day operations of the Secretariat throughout the year. All voting EC members act on a voluntary, non-remunerated basis. Regular teleconferences (TC) and three face-to-face meetings were organized in 2018 (see table below), with pre-set agenda items and relevant documents circulated in advance to facilitate informed decisions. A meeting facilitated by external consultants was held on 22nd of August, in Geneva, to discuss the proposal for the new 5-year strategy.

Notably, the following decisions were discussed and approved by the general assembly of members present on the afternoon of 29 October: the members approved the budget of USD 2 054 000 income and of USD 2 540 510 expenses for 2019, as presented by the Treasurer (see explanatory notes 1 and 2 on page 22). Thereafter, the president presented a new

5-year strategy for discussion and approval. The members voted on three main issues: (1) Membership fees shall increase in 2019 from USD 10 000 per year to USD 15 000 per year for full members, and from USD 5 000 to USD 12 000 per for prospective full members; (2) The mandate of the current EC shall be extended until the 2019 annual meeting, and (3) the EC shall be empowered to do all required to implement the proposed DCVMN 5-year strategy.

In 2018, twelve EC teleconferences or meetings were held: 29 January, 8 March, 16 April, 15 May, 13 June, 2 July, 21 and 22 August, 9 October, 16 October, 29 October, 17 December. Participation of EC members is shown in the table below. Gavi Board representatives attended two Gavi Board meetings and a Gavi Board retreat during calendar year 2018, in addition to Gavi teleconferences, when needed.

Role	Name	Company	Attendance out of 12 TC/or meetings
President and Gavi Alternate	Ms. Mahima Datla	Biological E	11
Vice-President	Dr. Alexander Precioso	Butantan	6
Treasurer	Mr. Fernando Lobos	Sinergium	12
Member	Mr. Steven Gao	Innovax	10
Member	Ms. Lingjang Yang	CNBG-Sinopharm	11
Member	Mr. Patrick Tippoo	Biovac	9
Member and Gavi Board representative	Mr. Sai Prasad	Bharat Biotech	4
Gavi PPC Member (non-voting)	Mr. Adar Poonawalla	Serum Institute of India	1
EC Senior Adviser (non-voting)	Dr. Akira Homma	Biomanguinhos	3
EC Senior Adviser (non-voting)	Dr. Suresh Jadhav	Serum Institute of India	11
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	12

Table 4. Governance statement.

Financial statements

Statement of income and expenditure for the year ended on 31 December 2018

	2018		2017	
INCOME	CHF	USD	CHF	USD
Memberships contributions	322,961.43	330,000.00	327,077.85	325,000.00
Donations	700,264.70	702,000.00	916,129.90	936,000.00
Annual meeting grant	0.00	0.00	63,593.95	65,500.00
Annual meeting participants' contribution	39,383.86	39,740.00	19,329.69	19,698.00
Other income	0.00	0.00	5.01	5.00
Income on investments	1,635.25	1,697.66	3,684.65	3,672.92
Gain on investments	0.00	0.00	22,396.90	22,747.21
Foreign exchange gain	24,735.00	22,417.31	0.00	0.00
TOTAL INCOME	1,088,980.24	1,095,854.97	1,352,217.95	1,372,623.13
EXPENSES	CHF	USD	CHF	USD
Salaries	137,792.00	139,039.99	162,190.25	162,390.02
Social contributions AVS/AI/APG/AC/PCFam	11,889.15	11,720.29	14,064.80	14,475.75
Social Insurances	2,746.85	2,865.68	3,282.75	3,282.17
LPP contribution	12,133.45	12,323.27	13,335.60	13,543.27
Office rental	7,211.64	7,310.91	6,311.52	6,318.60
Office insurance	389.10	390.35	343.35	337.81
Office supplies	2,940.81	2,997.62	4,583.20	4,624.35
Accounting services	15,368.85	15,657.63	14,369.40	14,770.76
Legal services	39,248.40	40,129.16	0.00	0.00
HR and payroll services	635.00	629.48	1,059.00	1,068.77
Strategic management consulting firm fees	409,860.00	405,000.00	0.00	0.00
Internal financial assessment	2,371.25	2,401.77	1,631.00	1,813.74
Mockaudit Initiative	103,344.83	104,339.12	259,558.99	264,300.34
Training Initiative	74,693.01	76,458.45	221,797.57	220,052.76
Regulatory Forum Initiative	41,282.30	41,374.76	58,010.89	58,891.26
Consulting Database	7,431.30	7,501.74	12,528.00	12,738.00
Publications	2,805.60	2,806.83	2,281.93	2,247.10
Travel expenses secretariat	13,175.32	13,500.09	21,397.11	21,414.60
Representation expenses	3,085.12	3,142.48	2,671.14	2,679.97
Executive Committee Meetings	7,004.00	7,199.16	2,071.00	2,110.36
Annual General Meeting	60,057.01	60,040.01	75,627.03	77,601.88
Miscellaneous	150.00	150.03	166.20	164.32
Interest paid	2.80	3.00	83.20	82.79
Bank and PayPal charges	3,674.43	3,750.69	3,554.78	3,599.99
Foreign exchange loss	0.00	0.00	59,337.99	59,645.81
Loss on investments	18,785.78	19,208.36	0.00	0.00
Provision for loss on membership contributions 2018	29,574.00	30,000.00	19,490.00	20,000.00
Reversal of provision for loss on members contributions 2017	-19,490.00	-20,000.00	0.00	0.00
Loss on memberships contributions 2016-2017	24,362.50	25,000.00	0.00	0.00
Taxes adjustment on year 2017	-618.35	-785.59	0.00	0.00
Taxes provision for 2018	12,893.75	13,377.28	12,588.65	13,004.68
TOTAL EXPENSES	1,024,799.90	1,027,532.56	972,335.35	981,159.10
SURPLUS	64,180.34	68,322.41	379,882.60	391,464.03

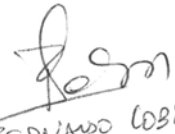
Explanatory Notes:

1. The Network's activities and interim financial statements (up to Q3 2018) were presented by the Executive Committee to the general assembly of members on 29 October, in Kunming, China, when the proposed 2019 activities and budget of USD 2 054 000 and USD 2 540 510, for income and expenses respectively, were approved by the assembly.
2. The approved income budget for 2019 was USD 2 054 000, based on the assumptions below:
 - a) the membership fees were expected to remain at the same level as 2018; however, after the budget approval the assembly approved an increase in membership fees. This might positively impact the total income due to membership fees, potentially doubling it, depending on the number of members in 2019.
 - b) an expected donation of approximately USD 65 000 from Imperial College, London, forecasted in 2018, was not received until January 2019, thus positively impacting the 2019 income.
 - c) Two grant donations of USD 475 950 and USD 1 080 000 scheduled for Q4 2018 were rescheduled for Q1 2019 to the down payment of USD 976'287 only for 2019. This will negatively impact the 2019 estimated income budget, as well as the estimated carryover from Q4 2018 was not realized.
3. The approved expense budget for 2019 was USD 2 540 510, and assumed a carryover amount of USD 544 491, corresponding to payments expected in Q4 2018 of 65 000 and 475 950 from donors (see above 1.b. and 1.c.) that were rescheduled for down payments in 2019. This will negatively impact the funds available for disbursement in support of grant activities for 2019. Thus, DCVMN might not be able to financially support grant activities allocated to the approved USD 1 555 950.
4. DCVMN revenue decreased by 20% in 2018 from USD 1 372 623.13 in 2017 to USD 1 095 854.97, (see balance table above). This was mainly due to a decrease of approximately USD 276 000 in donations (see below) while membership contributions remained stable. Notably, there was a USD 25 000 loss in membership contributions.
5. All income and disbursements are handled exclusively by bank transfers, providing independent and accurate accounting records and complying with international accounting and business practices. All disbursements are subject to a two-signature system, prepared by the Secretariat and approved by the Treasurer. All disbursements correspond to bank transaction records and invoices to services, controlled by an external accountant and controller. Accounts were reviewed and assessed by a finance professional from a corporate member, nominated by the Executive Committee.
6. Of note, in 2018 the USD/CHF exchange rate contributed to foreign exchange gain that reflected on the value of the dollar on 31 December 2018, as compared to the average exchange rate of the dollar over the calendar year. The indicated gains/losses and surplus are declared to the local fiscal authorities.
7. "Reversal of provision for loss on membership contributions 2017" indicates the debt of membership payments for 2016 and 2017 but not received from CIGB.
8. The financial statement was controlled by Multi-Fiduciaire Services, Geneva. (www.multigeneve.ch) and verified by internal assessment conducted by a financial manager in February 2019.

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

INCOME AND EXPENDITURE STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2018

<u>INCOME</u>	<u>2018</u>		<u>2017</u>	
	<u>CHF</u>	<u>USD</u>	<u>CHF</u>	<u>USD</u>
Memberships contributions	322'961.43	330'000.00	327'077.85	325'000.00
Donations	700'264.70	702'000.00	916'129.90	936'000.00
Annual meeting grant	0.00	0.00	63'593.95	65'500.00
Annual meeting participants' contribution	39'383.86	39'740.00	19'329.69	19'698.00
Other income	0.00	0.00	5.01	5.00
Income on investments	1'635.25	1'697.66	3'684.65	3'672.92
Gain on investments	0.00	0.00	22'396.90	22'747.21
Foreign exchange gain	24'735.00	22'417.31	0.00	0.00
Total income	1'088'980.24	1'095'854.97	1'352'217.95	1'372'623.13
<u>EXPENSES</u>				
Salaries	137'792.00	139'039.99	162'190.25	162'390.02
Social contributions AVS/AI/APG/AC/PCFam	11'889.15	11'720.29	14'064.80	14'475.75
Social Insurances	2'746.85	2'865.68	3'282.75	3'282.17
LPP contribution	12'133.45	12'323.27	13'335.60	13'543.27
Office rental	7'211.64	7'310.91	6'311.52	6'318.60
Office insurance	389.10	390.35	343.35	337.81
Office supplies	2'940.81	2'997.62	4'583.20	4'624.35
Accountant honorarium	15'368.85	15'657.63	14'369.40	14'770.76
Legal honorarium	39'248.40	40'129.16	0.00	0.00
HR and payroll services	635.00	629.48	1'059.00	1'068.77
Strategic management consulting firm fees	409'860.00	405'000.00	0.00	0.00
Internal financial assement	2'371.25	2'401.77	1'631.00	1'813.74
Mockaudit Initiative	103'344.83	104'339.12	259'558.99	264'300.34
Training Initiative	74'693.01	76'458.45	221'797.57	220'052.76
Regulatory Forum Initiative	41'282.30	41'374.76	58'010.89	58'891.26
Consulting Database	7'431.30	7'501.74	12'528.00	12'738.00
Publications	2'805.60	2'806.83	2'281.93	2'247.10
Travel expenses secretariat	13'175.32	13'500.09	21'397.11	21'414.60
Representation expenses	3'085.12	3'142.48	2'671.14	2'679.97
Executive Committee Meetings	7'004.00	7'199.16	2'071.00	2'110.36
Annual General Meeting	60'057.01	60'040.01	75'627.03	77'601.88
Miscellaneous	150.00	150.03	166.20	164.32
Interests paid	2.80	3.00	83.20	82.79
Bank and paypal charges	3'674.43	3'750.69	3'554.78	3'599.99
Foreign exchange loss	0.00	0.00	59'337.99	59'645.81
Loss on investments	18'785.78	19'208.36	0.00	0.00
Provision for loss on membership contributions 2018	29'574.00	30'000.00	19'490.00	20'000.00
Reversal of provision for loss on members contributions 2017	-19'490.00	-20'000.00	0.00	0.00
Loss on memberships contributions 2016-2017	24'362.50	25'000.00	0.00	0.00
Taxes adjustment on year 2017	-618.35	-785.59	0.00	0.00
Taxes provision for 2018	12'893.75	13'377.28	12'588.65	13'004.68
Total expenses	1'024'799.90	1'027'532.56	972'335.35	981'159.10
SURPLUS	64'180.34	68'322.41	379'882.60	391'464.03

Approved, 
 Fernand Lobo
 4/4/19

Innovative Technologies for Vaccines



Since 2000, the global vaccine market has tripled in size and several infections are newly preventable with vaccines against rotavirus, cervical cancer, pneumococcus, hand-foot-and-mouth disease, Ebola. As demand for vaccines has steadily increased, particularly in developing countries, the supply of affordable vaccines has become a high priority on the global agenda. Increasingly, developing countries vaccine manufacturers have stepped in to supply vaccines for developing countries use. Today, about 85% of the world's population is located in developing countries where vaccine demand continues to increase. DCVMN set the aim to increase the availability of high quality and affordable vaccines and to improve the coordination of vaccine supply coming from developing countries industry.

Through voluntary membership, Network corporate members have increasingly expressed their engagement, interest, willingness and commitment to meet global manufacturing standards by working to improve quality assurance systems, to consider opportunities for WHO prequalification (PQ), ensure regionally relevant vaccines are made and to respond to demand for specific vaccine products and presentations. This active engagement of industry from emerging markets represents a new window of opportunity to scale-up investments and foster a more secure and stable supply of vaccines. The successful Network initiatives, launched between 2014 and 2018, to strengthening DCVM regulatory and quality approaches, resulted in 15 corporate members

holding WHO prequalified vaccines for global supply, as compared to 6 in 2012. The Network is now well-positioned to provide members with access to consultation on facility design, tailored training on quality compliance, and expertise to improve specific processes. The Network is also a credible body to facilitate productive dialogue with regulatory experts and health authorities at WHO to ensure that the needs of developing countries are discussed and addressed in a productive manner.

The DCVMN Executive Committee took a step back to determine a path to achieve the aim of increasing the availability of high quality and affordable vaccines and improving the coordination of vaccine supply coming from developing countries. The organization will reset its approach, based upon feedback from the membership, to defining an organizational construct to foster sustainably. DCVMN will also engage in a three-year effort to help members manufacturers access the knowledge, tools, and skills required to attempt, achieve, and maintain WHO prequalification status for high priority vaccines.

In working together with our Partners, DCVMN secretariat is committed to embrace the development and promotion of innovative tools to foster better health for all.

Sincerely,

Sonia Pagliusi

DCVMN International
Executive Secretary



Developing Countries Vaccine
Manufacturers Network

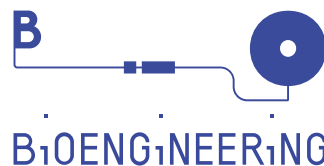
Acknowledgements

We are grateful to corporate partners for helping foster manufacturing excellence for the benefit of all people, facilitating knowledge sharing and intensifying training opportunities for a skilled industry

workforce in developing countries. The annual meeting and regional workshops held throughout 2018 were hosted in partnership with DCVMN partners here below.















**Imperial College
London**



**BILL & MELINDA
GATES foundation**

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