Developing Countries Vaccine Manufacturers Network

2017 Annual Report

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EXECUTIVE COMMITEE MEMBERS



Ms. Mahima Datla President Biological E. Limited, India



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



Mr. Fernando Lobos Treasurer Sinergium Biotech, Argentina



Mr. Sai D Prasad Bharat Biotech International Limited, India



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



Ms. Lingjiang Yang China National Biotech Group, 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,

I would like to take this opportunity to highlight some achievements of our members over the 2017 year: six new vaccines from the DCVMs received WHO PQ. These include Green Cross's Quadrivalent seasonal flu vaccine, Eubiologics' oral cholera vaccine (OCV) in plastic containers, Sinovac's Hepatitis A, Beijing-Bio's biOPV and Bharat Biotech's biOPV and typhoid vaccines. Our sincere congratulations to them.

We would also like to congratulate BioNet for receiving Thai FDA's approval for the world's only recombinant monovalent acellular pertussis vaccine and CNBG for receiving approval and production license for sabin IPV in China; Biological E and Zydus Cadila, for receiving Indian NRA approvals for MR vaccine, and Tetravalent Inactivated Influenza vaccine, respectively, and Panacea Biotec for the launch of its novel hexavalent vaccine.

In recent years, outbreaks of epidemics have highlighted our ill-preparedness for a rapid response and this is a serious global challenge. A number of initiatives, led by WHO, by CEPI and other organizations are bringing together experts and manufacturers to create the necessary framework on identifying risks and have mitigation strategies in place. DCVMs can make a strong contribution as many of us have relevant products in our portfolios and are working with stakeholders to set up a framework for rapid development, capacity planning and inventory holding strategies.



Innovation is very much needed to solve practical challenges, from imminent outbreaks to the last mile delivery. We are fortunate to join a new Partnership with the Future Vaccine Manufacturing Hub, in London, to advance the manufacturing and deployment of cost effective vaccines by designing new systems that can produce tens of thousands of doses of stable vaccines within weeks of a new threat being identified. At the same time, there is a need to strengthen awareness campaigns with greater social responsibility to keep trust in immunization at the highest level.

I thank you for your continued commitment and wish you all a new era of innovation!

Sincerely,

Mahima Datla DCVMN President

Millions of children set to be protected against typhoid fever

Gavi Board approves US\$ 85 million funding window for 2019-2020 to support the introduction of typhoid conjugate vaccine in developing countries



An immunisation session for the Hmong community at Nasala Village during a visit by the Gavi Board. Credit: Gavi/2017/Amanda Mustard.

November 30, 2017 - Millions of children in the poorest countries will soon be protected against typhoid fever following the Gavi Board's approval of support for typhoid conjugate vaccines.¹

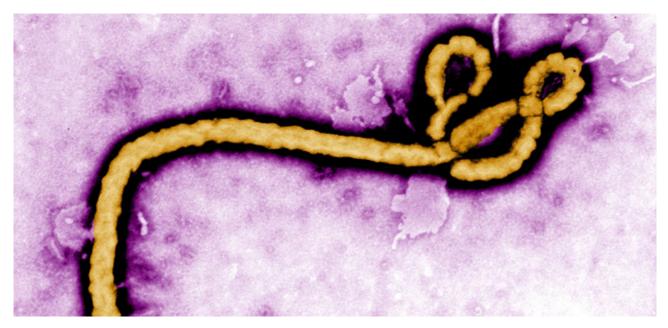
A serious enteric fever caused by ingesting contaminated food or water, typhoid fever killed more than 128,000 people in 2016 and affected nearly 12 million, according to the latest estimates. Improved living conditions and the use of appropriate antibiotics have resulted in the virtual elimination of the disease in industrialised nations and a dramatic global reduction in the proportion of deaths.

A new typhoid conjugate vaccine manufactured by Bharat Biotech International Limited and first licensed in India in 2013, received prequalification by the World Health Organization (December 2017) following the recent recommendation by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) that typhoid conjugate vaccines should be introduced in endemic countries to all children over six months of age. Vaccines from five additional manufacturers are also expected to be available between 2018 and 2022. Gavi expects the first countries to apply in 2018 with introductions forecasted to begin the year after.

¹ More information at <u>http://www.gavi.org/library/</u> news/press-releases/2017/millions-of-children-set-tobeprotected-against-typhoid-fever/

New Vaccine Hub puts scientists on frontline against disease outbreaks

Imperial College London centre aims to speed up development of vaccines ²



Source photo: Financial Times (<u>https://www.ft.com/content/afdc493e-e716-11e7-97e2-916d4fbacOda</u>)

December 27, 2017 - A £10 million vaccine development hub will be established at Imperial College London to help UK scientists respond more quickly to outbreaks of emerging infectious diseases caused by the likes of the Ebola and Zika viruses.

The Future Vaccine Manufacturing Hub will look to design a system that can produce tens of thousands of doses of a vaccine within weeks of a new threat being identified.

It will involve and will work with partners to ensure is impact. "We have engaged four UK universities and several relevant partners in the preparation of this proposal as initial stakeholders in our research programme, together with the Developing Countries Vaccine Manufacturing Network which represents 50 manufacturers in 17 countries", said Robin Shattock, Chair in mucosal infection and immunity at Imperial and the project leader. The hub offers a unique opportunity to enable researchers to rapidly respond to emerging epidemics.

² <u>https://www.timeshighereducation.com/news/</u> <u>new-hub-puts-scientists-front-line-against-disease-</u> <u>outbreaks</u>

http://gtr.rcuk.ac.uk/projects?ref=EP%2FR013764%2F1

DCVMN members' progress in global vaccines development and supply



Panacea Biotec introduced World's first Fully Liquid Hexavalent vaccine based on Whole-cell Pertussis (wP)

New Delhi, 30 March 2017 – EasySix[™] is a fully liquid ready-to-use hexavalent vaccine made using high quality antigens complying with WHO's cGMP requirements. The vaccine is indicated for primary immunization to protect newborns against six common preventable diseases: Diphtheria, Tetanus, Whooping Cough, H. Influenza type b Meningitis, Epiglottitis and Pneumonia, Hepatitis B and Poliomyelitis. EasySix is found to be immunogenic, safe and well tolerated in Phase I and Phase III clinical trial In India. The fully liquid 6-in-1 combination vaccine.

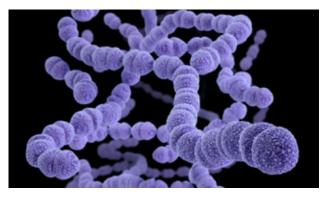
EasySixTM requires no reconstitution, therefore saves time, is convenient, easy to administer and minimizes chances of error.

Panacea Biotec is acknowledged by the UN Health Agencies in partnering for the Polio eradication program and has supplied billions of doses of WHO Pre-Qualified Polio vaccines across the Globe.

More information at:

http://vaccinebox.com/easysix-a-new-efficient-vaccine-to-takecare-of-6-preventable-diseases-in-oneshot-is-launched-now/

http://www.business-standard.com/article/ news-cm/panaceabiotec-launches-easysix-vaccine-117032900559_1.html



Biovac and PATH announce partnership to develop novel vaccine against GBS infection

South Africa, 2 May 2017 – The South Africabased Biovac Institute and PATH, an international health organization, are pleased to announce the launch of a collaborative partnership to develop a novel vaccine against Group B Streptococcus (GBS), supported by a grant from the Bill & Melinda Gates Foundation.

GBS is a leading cause of severe infection in newborns and young infants in many countries, including South Africa. The estimated incidence of invasive GBS disease in South Africa is among the highest, with 2.38 cases per 1,000 live births. Whilst people of all ages can contract the GBS bacterial infection, newborns are more susceptible and vulnerable to this potentially deadly infection-particularly as an estimated 1 in 4 pregnant women carries the GBS bacterium, which can be passed to babies during birth. In the developing world, mortality rates can reach as high as 38 percent. Babies who survive the disease are often left with lifelong disabilities such as deafness, blindness, and developmental delays. A vaccine against GBS would be revolutionary in that it would be given to pregnant mothers who would pass on the protective antibodies to their babies, ensuring protection at birth and during the first critical months of life (when late-onset GBS disease is a risk).

More information at: http://www.path.org/news/press-room/812/

DCVMN International





Relocation of INNOVAX's Headquarters

Xiamen, 18 November 2017 – This new facility is designed according to WHO prequalification requirements, which is built to meet the highquality production of vaccines for people in need. At the same time, it aims to provide an environmental friendly place for each employee to work and to contribute. The state of art facility is expected to be in full operation by 2019.

With relocation to the new headquarter, INNOVAX will hold to its mission of developing, manufacturing and marketing innovative vaccines, and continue its commitment to: "Increase the availability of high quality innovative vaccines to combat infectious diseases globally." With this effort, we also believe INNOVAX will be constantly growing.

More information at: <u>http://www.innovax.cn/en/news_view.aspx?news-</u> <u>Cateid=56&cateid=56&NewsId=899</u>

WHO's prequalification of a bivalent oral polio vaccine from Beijing-Bio Institute of Biological Products (BBIBP)

Geneva, 21 December 2017 – In April 2016, following the eradication certification of type 2 polio, countries using trivalent OPV implemented a global switch to bOPV, which protects against polio types 1 and 3. The Global Polio Eradication Initiative recommends biOPV use in polio-endemic and other high-risk countries because it prevents disease transmission (unlike inactivated polio vaccine, which only protects the person vaccinated) and it is easier and more cost-effective to deliver.

High-risk countries will require billions of doses of biOPV every year for routine immunization and vaccination campaigns to develop population immunity, to stamp out pockets of endemic, wild-poliovirus transmission, and to control outbreaks. The addition of another affordable biOPV product will improve access among the populations who need it most now and for years to come. BBIBP received support from DCVMN in 2016 for the final phase of the prequalification process, to establish the pharmacovigilance system that enables powerful data collection and surveillance of vaccines distributed globally.

More information at: http://www.path.org/news/pressroom/857/

https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=319



World's First Typhoid Conjugate Vaccine from Bharat Biotech, Prequalified by WHO

Hyderabad, 22 December 2017 – Bharat Biotech's Typbar TCV®, the world's first clinically proven Typhoid Conjugate Vaccine against typhoid fever has received prequalification from World Health Organisation (WHO). This enables the procurement and supplies of this life saving vaccine to UNICEF, Pan-American Health Organization (PAHO) and GAVI supported countries. Typbar TCV® has been evaluated in Human Challenge Studies at Oxford University and typhoid conjugate vaccines have been recommended by WHO's Strategic Advisory Group of Experts on Immunization (SAGE).

International Health Metrics and Evaluation (IHME) estimates that in 2016, there were approximately 12 million cases of typhoid fever resulting in around 130,000 deaths. Typhoid fever is caused by the bacterium Salmonella Typhi (S. Typhi), which infects humans due to contaminated food and beverages from sewage and other infected humans.

"Typbar TCV[®] is the first typhoid vaccine, clinically proven to be administered to children from 6 months of age to adults and confers long term protection against typhoid fever", said Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech.

More information at: http://www.bharatbiotech.com/images/press/Bharat_Biotech_2018_pressrelease1.pdf



Sinovac Biotech gets approval from WHO for its Hepatitis A vaccine

Beijing, 22 December 2017 – Sinovac Biotech Ltd., a leading provider of biopharmaceutical products in China, announced that it has received a positive decision from the World Health Organization on the acceptability of its Healive, a hepatitis A vaccine product, for purchase by United Nations agencies.

The Company's Healive product was assessed according to the WHO Prequalification Procedure. Mr. Weidong Yin, Chairman, President and CEO of the Company, commented that "I am very pleased that Healive has passed the assessment under WHO Prequalification procedures. This is an important milestone for Sinovac which we expect will provide opportunities to supply this vaccine to respective UN agencies as well as accelerate the regulatory approval process for this vaccine in international countries outside China."

More information at:

http://www.sinovac.com/?optionid=754&auto_ id=848

http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/

Expert Webinar Series: real time engagement



A series of 10 webinars was held throughout the year 2017. Subject matter experts were invited by DCVMN to share their views and knowledge with our members, taking advantage of the power of online Webex communication platform technology. There were 200 connecting participants throughout the year, whereby some participants connected as a group to attend the webinars.

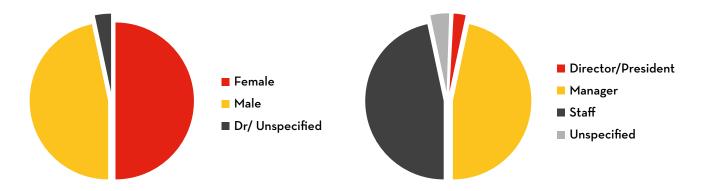
Date	Торіс	Presenter (affiliation)	Number of connections*
10 January	The new DCVMN E-learning Platform	C. Ting (DCVMN)	16
14 February	Type 1 Glass for pharmaceutical containers: technical requirements and regulatory updates	Dr. D. Zuccato (Ompi)	23
O8 March	Improving access to vaccines: the role and progress of vaccine price transparency	S. Mariat (WHO)	10
26 April	Establishing Benchmarks for Vaccine Introduction & Uptake Timing in Gavi- Countries	Dr.L.Privor-Dumm (John Hopkins/ IVAC)	15
29 June	Creative Capacity: Innovative solutions for the future of bioproduction	S. Frie (GE Healthcare)	26
13 July	Technology Transfer at IVI	Dr. V. Pavliak (IVI)	21
17 August	GAP III: minimizing poliovirus facility-associated risk	Dr. P. Minor (NIBSC)	32
17 September	Characterisation of Sabin based inactivated polio vaccines	J. Westdijk & G.Kersten (Intravacc)	24
12 October	Innovative Cell culture & purification approaches to cost-effective manufacturing of viral vaccines	B. Damien (Univercells)	11
07 December	Improving pharmacovigilance: regulatory outlook and Argus safety database	F. Kjøller, N. B. Leander & P. S. Pallesen (NNIT)	38

Table 1. Summary of DCVMN hosted Webinars 2017.

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

Fostering Gender Balance

in developing countries' vaccine industry through professional training



Schematic representation of statistical analyses of participants at DCVMN training workshops during 2017. Left panel shows the percentage of male (yellow) and female (red) participants (a small percentage of participants did not identify their gender (black)). Right panel depicts the professional role as to responsibility level of participants.

During the year 2017, DCVMN together with its partners organized a series of professional training workshops, focusing on several topics of Quality Management Systems, as well as other cross-cutting topics. The workshops aim to bring updates to professionals from DCVMN corporate members on current GXP and technology trends for manufacturing and supplying high-quality vaccines.

In total, 406 participants attended regional workshops in 2017, where ca. 45% were male and ca. 50% were female, from 41 companies and 13 countries. Statistics also show that the training workshops benefit most technical staff and middle level managers, the people directly involved with production, quality control and quality assurance. The location, topic and attendance of all regional workshops are shown inTable 2 below. Eleven out of the 406 individuals attended more than one workshop, and one individual attended more than two workshops, indicating an equitable nature of the training opportunities, as a broad group of manufacturing professionals are benefitting, not favouring just a few individuals repeatedly.

Follow-up in-house training sessions, organized by member companies after regional workshops, disseminated the knowledge, benefiting in addition ca. 1360 individuals (an increase compared to 1053 people in 2016). In 2017 the "train-the-trainer" initiative reached 1769 vaccine professionals across the globe (as compared to 1510 participants in 2016).

Date	Location	Торіс	Nº of participants	Follow-up reported	Total
15-19 January 2017	Dhaka, Bangladesh	Quantitative and Qualitative Vaccine Analysis	61	123	184
6-10 March 2017	Taipei, China	Global registration and supply shortages	48	99	147
20-24 March 2017	Hanoi, Vietnam	Facility design concept and quality/production validation and development	63	188	251
3-7 April 2017	Hyderabad, India	Internal audit/ Third party au- dit/ Supply chain management	67	220	287
8-12 May 2017	Beijing, China	Vaccine Safety and Pharmaco- vigilance Management	72	520	592
20-26 June 2017	Rio, Brazil	Biosafety and cleanroom behaviour	47	70	117
17-21 July 2017	Bangkok, Thailand	Clinical studies management	48	143	191
TOTAL			406	1363	1769

Table 2. DCVMN training workshop in 2017. These efforts are partly supported by a grant from the Bill and Melinda Gates Foundation (Grant no. OPP 1113279).



Group visit to Medigen's new plant in Taipei, March 2017, following a training workshop.

Annual report 2017



Hyderabad workshop participants, April 2017.



Beijing workshop participants, May 2017.



Training workshop in Brazil, June 2017.



DCVMN delegates visit to Taiwan FDA, on the occasion of the Taipei workshop 2017.

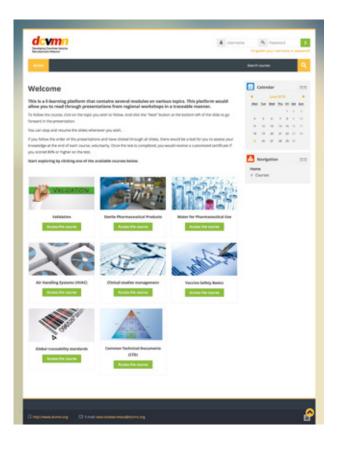


Bangkok workshop participants, July 2017.



Hanoi workshop participants, March 2017.

DCVMN's New E-learning Platform



In 2017, seven E-learning modules were available on the open DCVMN E-learning platform, with the aim of disseminating information, supporting the training workshops, as well as facilitating knowledge sharing in follow-up in-house training sessions among DCVMN corporate members.

The platform allows DCVMN members to freely access freely to online materials for self-learning. After completing each module, a self-evaluation with automatic correction enables users to test their knowledge on the respective topic; then a customized certificate can be downloaded for each module completed, if users score 80% or higher on the self evaluation.

Available E-learning materials have been kindly shared by WHO, GS1 and Dr. S. Viviani, and include to date: Air Handling System (HVAC), Clinical Studies Management, Global Traceability Standards, Sterile Products, Vaccine Safety Basics, Validation, Water for Pharmaceutical Use.

DCVMN is proud to promote and encourage a culture of continuous improvement to all members through the use of the open E-learning platform for personal development.

More information available at

Module	Nº Participants	N° Certificates achieved	% of Certificates achieved
Vaccine Safety Basics	80	18	22.50%
Sterile Pharmaceutical Products	145	87	60.00%
Water for Pharmaceutical Use	69	33	47.83%
Air Handling Systems	64	35	54.69%
Validation	95	31	32.63%
Clinical studies management	81	20	24.69%
Global traceability standards	21	9	42.86%
TOTAL	555	233	

https://moodle.dcvmn.net

Table 3. Participation in the new E-learning Platform.

Vaccines: Inspiring Innovation

DCVMN Annual Meeting 25-28th September, Seoul, S. Korea

The Honorable Deputy Minister of Health and Welfare, Deok Cheol Kwon, addressed the delegates by video, recognizing the value and importance of vaccines, as a part of efficient public health and security systems, and the efforts at the government and corporate levels. He highlighted that this was the first AGM held in Korea, hosted by SK Chemicals and co-hosted by IVI, playing and important role in global health, to reduce morbidity and mortality from infectious diseases.



Honorable Deputy Minister Deok Cheol Kwon at the opening session.

For its 18th Annual General Meeting in Seoul, DCVMN gathered leading representatives of the Korean Health Authorities, International Vaccine Institute, World Health Organization, UNICEF and other global health stakeholders to foster innovation through open dialogue with vaccines' manufacturers.

Inspiring innovation for vaccines requires collective efforts that were openly discussed among leading experts and panel discussions during the following topics:

- Epidemic & Pandemic
- Technology transfer
- Innovative Partnerships
- New Polio Vaccines
- Regulatory Convergence
- Innovative Vaccines
- Procurement & Financing
- WHO prequalification

Opening Session and Inaugural Speeches



DCVMN members and delegates at the opening session.



Welcome note by Executive Vice President, J.Y. Ahn, SK Chemicals.



Opening speech by DCVMN President, M. Dattla.



DCVMN International

















Upper row: left Kenote by CEO Gavi, S. Berkley; right: Lecture by IVI General Director,J.Kim. Second row: left , S.Briand, WHO; right, A.Oswald, BMGF. Third row: left, Lecture by CEPI CEO, R.Hatchet; right, S.Rautio, UNICEF. Fourth row: left, O.Vargas, PAH RF; right, M.Friede, WHO.

Views and opinions

from CEOs and leading experts around the world











DCVMN International











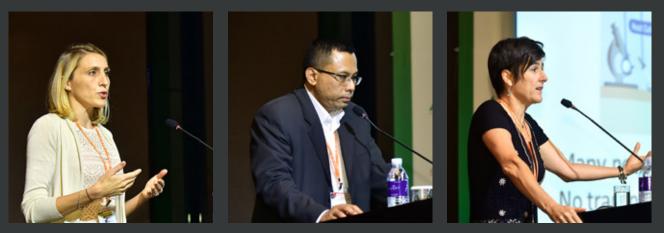












Governance statements

The Executive Committee reviews, advises and approves, on behalf of members, the day-to-day operations of the Secretariat throughout the year. Regular teleconferences (TC) and two face-to-face meetings are organized annually, structured with pre-set agenda items and relevant documents circulated in advance to facilitate informed decisions. All voting Executive Committee members act on a voluntary, non-remunerated basis. In addition, DCVMN representatives appointed as senior advisers to the Executive Committee , as well as the GAVI Board representatives are invited. In 2017 there were eight Executive Committee teleconferences or meetings: January 24th, February 16th, March 13th, April 24th, June 14th, August 28th, September 25th, December 04th. Participation of executive committee members is shown in the table below. Gavi Board representatives attended two Gavi Board meetings and a Gavi Board retreat within the calendar year 2017. At the general assembly on 25th September 2017 in Seoul, the members approved the budget of 657.000 USD for 2018, presented by the treasurer. Members welcomed the location of the next DCVMN AGM 2018, to take place in Kunming, China, hosted by IMBCAMS.

Role	Name	Company	Attendance out of 8 TC/or meetings
President and Gavi Alternate	Ms. Mahima Datla	Biological E	5
Vice-Presi dent	Dr. Alexander Precioso	Butantan	1
Treasurer	Mr. Fernando Lobos	Sinergium	7
Member	Mr. Steven Gao	Innovax	6
Member	Ms. Lingjang Yang	CNBG-Sinopharm	7
Member	Mr. Patrick Tippoo	Biovac	7
Member and Gavi Board representative	Mr. Sai Prasad	Bharat Biotech	6
Gavi PPC Member (non-voting)	Mr. Adar Poonawalla	Serum Institute of India	1
EC Senior Adviser (non-voting)	Dr. Akira Homma	Biomanguinhos	2
EC Senior Adviser (non-voting)	Dr. Suresh Jadhav	Serum Institute of India	6
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	8

 Table 4. Governance statement.

Financial statements

Statement of Income and Expenditure for the year ended on 31st December 2017

INCOME AND EXPENDITURE STATEMENT FOR THE YEAR ENDED 31 DECEMBER

	2017		2016	
INCOME	CHF	USD	CHF	USD
Members contributions	327'077.85	325'000.00	320'078.52	320'030.00
Donations	916'129.90	936'000.00	892'340.40	906'000.00
Annual meeting contribution	63'593.95	65'500.00	64'800.85	65'888.00
Annual meeting contribution participants	19'329.69	19'698.00	14'844.76	15'100.00
Other income	5.01	5.00	2'400.11	2'423.37
Income on investments	3'684.65	3'672.92	4'376.70	4'566.66
Gain on investments	22'396.90	22'747.21	7'422.02	7'535.05
Foreign exchange gain	0.00	0.00	27'861.18	23'062.06
Total income	1'352'217.95	1'372'623.13	1'334'124.54	1'344'605.14
EXPENDITURES				
Salaries	162'190.25	162'390.02	133'169.90	134'011.05
Social contributions AVS/AI/APG/AC/PCFam	14'064.80	14'475.75	11'300.90	11'361.45
Social Insurances	3'282.75	3'282.17	2'718.45	2'688.35
LPP contribution	13'335.60	13'543.27	13'917.30	14'024.71
Office rental	6'311.52	6'318.60	6'279.12	6'324.83
Office insurance	343.35	337.81	381.45	377.60
Office supplies	4'583.20	4'624.35	5'678.22	5'708.67
Account Honorarium	14'369.40	14'770.76	13'721.40	13'738.89
HR and payroll services	1'059.00	1'068.77	721.50	726.59
Internal financial audit	1'631.00	1'813.74	4'911.00	4'805.10
Mock audit Initiative	259'558.99	264'300.34	272'884.43	273'526.06
Training Initiative	221'797.57	220'052.76	223'699.94	225'738.89
Regulatory Forum Initiative	58'010.89	58'891.26	60'851.29	61'230.72
Consulting Database	12'528.00	12'738.00	9'936.00	10'030.13
Publications	2'281.93	2'247.10	1'913.70	1'945.72
Travel expenses secretariat	21'397.11	21'414.60	11'230.76	11'361.23
Representation expenses	2'671.14	2'679.97	1'502.55	1'509.70
Executive Committee Meeting	2'071.00	2'110.36	2'370.00	2'425.50
Annual General Meeting	75'627.03	77'601.88	78'902.36	80'014.67
Miscellaneous	166.20	164.32	50.00	49.60
Interests paid	83.20	82.79	27.65	27.20
Bank and paypal charges	3'554.78	3'599.99	3'623.61	3'678.89
Foreign exchange loss	59'337.99	59'645.81	0.00	0.00
Provision for loss on members contributions	19'490.00	20'000.00	0.00	0.00
Taxes on previous year	0.00	0.00	-117.50	225.59
Taxes _	12'588.65	13'004.68	10'000.00	9'838.65
Total expenditures	972'335.35	981'159.10	869'674.03	875'369.79
SURPLUS	379'882.60	391'464.03	464'450.51	469'235.35
		CONTRACTOR CONTRA		

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Notes: DCVMN revenue only increased by 2% in 2017, from 1'344'6O5 USD to 1'372'623.13 (see Balance table above). This was mainly due to substantial foreign exchange losses (see below), accumulated debt of membership fees of a member, while balanced by small gains on investments, as memberships, partnerships and private donations remained similar to the previous year. One new member joined the Network in 2017: Saint Petersburg Institute.

At the last quarter of the calendar/financial year the network's activities and interim financial statements were presented by the Executive Committee to the general assembly of members, on September 25th, in Seoul, Korea, when the proposed 2018 activities and budget of 657.000 USD were approved by the assembly.

All income and disbursements are handled exclusively by bank transfers, providing independent and accurate accounting records, complying with international accounting and business practices. All disbursements are subject to two-signature system, prepared by the Secretariat and approved by the Treasurer. All disbursements correspond to bank transactions records and invoices to services, controlled by an external accountant and comptroller. Accounts were audited by an internal professional auditor nominated by the Executive Committee.

Of note, in 2017 the dollar devaluation compared to Swiss franc has contributed to foreign exchange losses that reflect the value of the dollar on 31st December 2017, as compared to the average exchange rate of the dollar over the calendar year.

In income, the item "provision for loss on members' contributions" indicates the debt of membership payments not received from CIGB for 2016 and 2017. Item "foreign exchange loss" indicates the difference between the exchange rate applied during the year and the exchange rate on 31.12.2017 according to the tax payable on 31.12.2017 revaluation rate. The indicated gains/losses and surplus are declared to the local fiscal authorities.

Responsible Innovation for Vaccines

Together with our Partners, DCVMN is committed to develop and promote Responsible Innovation



Responsible Innovation is a process that seeks to promote creativity and opportunities for science and innovation that are socially desirable and undertaken in the public interest. ⁴

Responsible Innovation creates spaces and processes to explore aspects of innovation in an open, inclusive and timely way. This is a collective responsibility, where stakeholders and the public have an important role to play. It includes, but goes beyond, considerations of risk and regulation, important though these are.

We embrace the responsibility to ensure that our activities, our partners and the manufacturers we serve, are aligned with the principles of Responsible Innovation, creating value for society in an ethical and responsible way, through innovative vaccines. We strive to provide the best knowledge, the best approaches, the best technologies, and the best opportunities for sustainable development of novel vaccines for protecting people, communities and countries.

Sonia Pagliusi Executive Secretary



Developing Countries Vaccin Manufacturers Network

⁴ <u>https://epsrc.ukri.org/research/framework</u>

Acknowledgements

We are grateful to corporate partners for helping foster manufacturing excellence for the benefit of all people. To facilitate knowledge sharing and intensifying training opportunities for a skilled industry workforce in developing countries, the annual meeting and regional workshops held throughout 2017 were hosted in partnership with DCVMN corporate partners here below.



We thank SK Chemicals for hosting and supporting the general annual meeting 2017, and the Bill and Melinda Gates Foundation for a conference Grant to DCVMN (grant no. OPP1157021).

