



Developing Countries Vaccine  
Manufacturers Network



# 2019 Annual Report



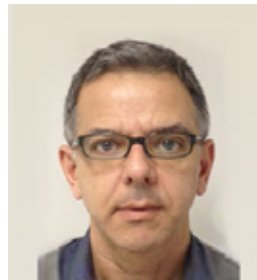
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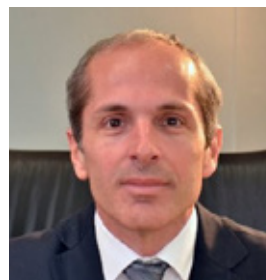
## EXECUTIVE COMMITTEE MEMBERS



**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. Patrick Tippoo**  
The Biovac Institute, South Africa



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



**Dr. Sonia R Pagliusi**  
Executive Secretary  
DCVMN International

# Message from the President



## Dear DCVMN members,

I would like to underline here some achievements of our group members and of DCVMN as an enabler.

To date, 15 Network members manufacturers supply WHO pre-qualified vaccines, and 7 new vaccines have received PQ in 2019: MR from Biological E; IPV and PCV from Serum; mOPV type 2 from BioFarma; cell-based influenza and varicella from SK biosciences and rabies from Zydus Cadila. With these additions, the number of WHO prequalified vaccines from DCVMN members jointly is 76, accounting for 50% of the total vaccines prequalified by WHO.

I would also like to highlight that DCVMN International was awarded a grant of nearly 2.3 million USD on January 07th 2019, to continue promote the stable and sustainable supply of quality vaccines to developing countries to scale up global immunization. Other highlight is that LG Chem received a \$33.4 million grant from the Gates Foundation to develop a 6-in-1 combination vaccine to prevent childhood diseases. Additional funding news is that increased membership contributions, approved by the members in 2018, was implemented in 2019, resulting in ca. 70% increase in income contributions from members, compared to 2018.

Building on our 5-year strategic plan, the executive committee is proceeding with separation of governance from execution roles. A draft project for updating the statutes & bylaws will be communicated to members early 2020 and help reorganize functions and responsibilities. The Secretariat has engaged three senior consultants to help build specific working areas, support members in active engagements on global health issues, facilitate continuous training and perform surveys to ensure our work reflects the needs of the constituency.

Pre-qualification continues to be our focus and in line with it, informal meetings with WHO PQ, RSS & Safety Blueprint are the most regular. DCVMN keeps cordial relations with WHO DG office, ADG office,

PIP and with the WHO NCL network. The AGM keeps open slots for WHO, UNICEF, PAHO, GAVI, Gates foundation, CEPI and other stakeholders, and this has been appreciated. Their participation adds immense value towards learning for Network members and towards finding an important common platform for open discussions on challenges that we face today as a vaccines industry organization. I congratulate Fiocruz/BioManguinhos for successfully hosting the 20th Annual General Meeting, under the theme of "Vaccines, Innovations for good". On behalf of every member of DCVMN, I would also like to thank our donors and corporate partners for their support throughout the years.

It has been three years for me serving as the President of the Network and have received tremendous support from the Executive Committee and the Secretariat in conducting the Network's business. I take this opportunity to personally thank each and every one of you for your invaluable contributions directly or indirectly over the last three years. I also want to acknowledge the tremendous efforts of the Grant Advisory Committee and the Secretariat for ensuring success in achieving DCVMN's goals with respect to training and knowledge exchange.

We are at crossroads where despite significant progress on expanding global immunization, coverage has stalled at about 85% in recent years. It falls on not just the institutions implementing the programmes, but on every stakeholder to think out-of-the-box and provide innovative solutions to overcome this highest hurdle. It is imperative to work towards accessibility without compromising on the sustainability of DCVMs.

Your enthusiasm and commitment is going to be crucial to carry this important mission forward.

Sincerely,

**Mahima Datla**  
DCVMN President

## WHO Director General addressed the delegates of the DCVMN Annual General Meeting 2019



*Dr. Tedros Ghebreyesus, Director General of the World Health Organization - shot from the video displayed in Rio.*

**Rio de Janeiro, 22<sup>nd</sup> October 2019** – On the occasion of the 20<sup>th</sup> Annual General Meeting of the Developing Countries Vaccine Manufacturers Network (DCVMN), held in Brazil, WHO Director General, Dr. Tedros Ghebreyesus, addressed the delegates by video. He highlighted that “vaccines are one of the most accessible and cost-effective tools in the history of healthcare. Smallpox has been eradicated, polio is on the brink of eradication, and millions of lives have been saved from measles, meningitis and other diseases thanks to vaccines.” However, many children are missing out vaccination, and preventable diseases are still a major cause of illness and death. Low and middle-income countries have been slower in adopting vaccines than high-income countries, and one of the barriers to access include the lack of resources and regulatory systems.

He commended the DCVMN members for making a vital contribution to increasing the quality, availability and affordability of vaccines. There are now

over 70 WHO prequalified vaccines from DCVMN members, including rotavirus, yellow fever, cholera and more.

He added that “our next challenge is to use collaborative ways to translate these vaccines availability into national licences for use in countries. Low resources, heavy workload and untrained staff in many countries mean that vaccines take longer to reach children.” He thanked DCVMN and all its Partners, Gavi, UNICEF, Gates Foundation and others, for their support and commitment. “Together we can overcome the barriers we face, and ensure that all children enjoy the lifesaving power of vaccines” he concluded.

More information at:

[www.dcvmn.org/2019-Annual-meeting-in-Rio-de-Janeiro-367](http://www.dcvmn.org/2019-Annual-meeting-in-Rio-de-Janeiro-367)



## PAHO Director highlights achievements and challenges in vaccine production



*Minister of Health of Brazil, Luiz Henrique Mandetta and Dr. Carissa F. Etienne, PAHO Director, discussed challenges and achievements in vaccine production, in Rio de Janeiro, Brazil.*

**Rio de Janeiro, 22<sup>nd</sup> October 2019** – The Director of the Pan American Health Organization (PAHO), Carissa F. Etienne, during the opening of the 20<sup>th</sup> General Meeting of the Developing Countries Vaccine Manufacturers Network (DCVMN), in Rio de Janeiro, highlighted the achievements and challenges of vaccine production.

“I see this Network as a global public good, a network of manufacturers and innovators that have assumed the principle of collective action and solidarity, to protect global health. The vaccines you produce protect and promote the health of millions in this Region (Americas), and globally”, she stated. The PAHO Director also encouraged the network of producers to continue efforts to invest in new vaccines that have high quality and are affordable. “And more importantly,” she added, “I urge you to ensure and protect the global supply of the more ‘traditional and well established’ vaccines that are becoming less attractive commercially.”

Maurício Zuma, Director of the Instituto de Tecnologia em Imunobiológicos (Bio-Manguinhos/Fiocruz), added the meeting aims are to share experiences and discuss capabilities, financing, supply, regulatory issues, alliances, partnerships, innovations, among other topics. “Our vaccines have prevented

the spread of several diseases and saved millions of lives each year. It makes us proud. But we are aware of our responsibility and we know that innovation is key to our survival in the long term,” he said.

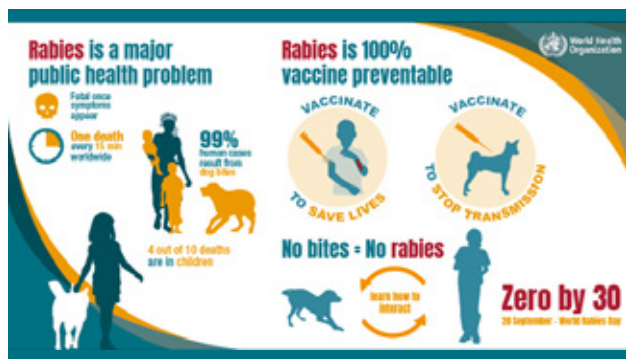
President of the Oswaldo Cruz Foundation (Fiocruz) Nísia Trindade de Lima said that vaccination is a human right. “In a context where market monopolization can make vaccines inaccessible to the majority of the population, it’s up to us to affirm vaccination as a public good and one of the main achievements for everyone’s right to health and disease prevention,” she added.

The Minister of Health of Brazil, Luiz Henrique Mandetta, announced during the event that after three years of discontinuation of yellow fever vaccine exports, Brazil will resume international supply. Between 2017 and 2018, the country had yellow fever outbreaks and suspended its vaccine exports, focusing all its production for the Brazilian population. “Another important step we are taking, is the construction of the Health Biotechnology Industrial Complex. It will include multiple platforms that can produce different types of vaccines, quickly responding to domestic needs”, said Mandetta.

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



### Zydus Cadila receives WHO prequalification for Vaxirab - N

**Geneva, 07<sup>th</sup> February 2019** – Vaxirab N, the rabies vaccine manufactured by Zydus Cadila, a leading innovation-driven global healthcare provider, has received prequalification from the World Health Organization (WHO).

In 2008, the group received WHO prequalification for its purified duck embryo rabies vaccine, Lyssavac N - the (PDEV), for purchase by various United Nations Agencies. With this, Zydus became the first Indian pharma company, and the second pharma company in the world, to receive WHO prequalification for rabies vaccine. Zydus subsequently migrated to the purified chick embryo cell rabies vaccine, Vaxirab N, and shall contribute to global supply to save lives and achieve the goal set by WHO of zero human deaths from rabies by 2030.

Zydus Cadila develops vaccines for routine vaccination programmes such as diphtheria, pertussis, tetanus, Haemophilus influenzae type b, hepatitis B, measles, mumps, rubella, varicella, influenza and typhoid fever. In addition, Zydus' Vaccine Technology Center is developing new vaccines such as human papillomavirus, leishmaniasis, malaria, haemorrhagic Congo-Crimea fever, Ebola and Japanese encephalitis.

More information at:

[apps.who.int/iris/bitstream/handle/10665/272756/9789241513838-eng.pdf?ua=1](https://apps.who.int/iris/bitstream/handle/10665/272756/9789241513838-eng.pdf?ua=1); or <https://www.who.int/en/news-room/fact-sheets/detail/rabies-vac-green-light-to-manufacture-vaccines/>

### First cell-culture based influenza vaccine received WHO Prequalification

**Geneva, 8<sup>th</sup> April 2019** – The cell-culture based influenza vaccine, manufactured by SK bioscience, received World Health Organization (WHO) prequalification. The cell-based flu vaccine was developed as an alternative to the egg-based manufacturing process. The influenza viruses used in the cell-based vaccine are grown in cultured cells of mammalian origin.

“Cell culture technology is potentially more flexible than the traditional technology, which relies upon adequate supply of pathogen-free eggs. In addition, the cell-based flu vaccine that uses cell-based candidate vaccine viruses (CVVs) has the potential to offer better protection than traditional egg-based flu vaccines as a result of being more similar to flu viruses in circulation.” mentions the US Center for Disease Control and Prevention (cf. <https://www.cdc.gov/flu/protect/vaccine/cell-based.htm>). SK bioscience has launched the world's first cell-culture influenza vaccine for children and adolescents between the ages of 6 months to 18 years, as well as the world's second for adults, back in 2014. With the prequalification, the WHO enables healthcare providers around the globe to stop the spread of influenza and access to the vaccine, enhancing prevention options.

More information at:

[www.cdc.gov/flu/protect/vaccine/cell-based.htm](https://www.cdc.gov/flu/protect/vaccine/cell-based.htm)





## LG Chem received a grant from the Gates Foundation to develop a 6-in-1 combination vaccine to prevent childhood diseases

**Seoul, 11<sup>th</sup> March 2019** – LG Chem announced that it will receive support from the Bill & Melinda Gates Foundation for the development of a hexavalent vaccine to prevent six diseases – diphtheria, tetanus, whooping cough (pertussis), hepatitis B, Haemophilus influenzae type b, and polio.

“Many young children worldwide are still exposed to various kinds of infectious diseases because they miss inoculation schedules,” said Jee-won Son, head of the firm’s life sciences division. LG Chem explained that, thus far, no such combination vaccine has been prequalified by the World Health Organization (WHO). “We are preparing for a second phase clinical trial and planning to supply it to UNICEF and other organizations after 2023”, the firm said. The 6-in-1 vaccine is anticipated to improve vaccination coverage globally.

This is the second grant the firm has received from the Gates Foundation. In 2017, it received USD \$19,504,126 to develop Sabin inactivated poliovirus vaccine (sIPV). “The polio vaccine is currently in phase three of clinical trials and is scheduled to hit the market in 2021” the official said, adding it expects it will solve worldwide issues for polio vaccines.

LG Chem was the first Korean company to produce a genetically modified hepatitis B vaccine, Euvax, which has been supplied to more than 200 million infants globally through UNICEF.

Excerpts taken from:

[koreatimes.co.kr/www/tech/2019/03/133\\_265162.html](http://koreatimes.co.kr/www/tech/2019/03/133_265162.html)

## A New Cholera vaccine in the horizon

**New Delhi, 26<sup>th</sup> June 2019** – Bharat Biotech is honoured to have joined hands with Hilleman Laboratories for the development, manufacture and commercialization of Hillchol, its Oral Cholera Vaccine.

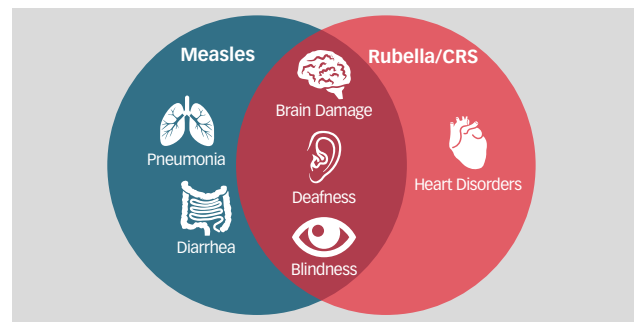


Dr. Gil (Hilleman Laboratories) and Dr. Ella (Bharat Biotech) announcing the collaboration

The development process included demonstration of safety and immunogenicity in an age de-escalating phase I/II clinical trial conducted in Bangladesh.

More information at:

[www.hillemanlabs.org/resources/news/hilleman-laboratories-licenses-oral-cholera-vaccine-hillchol-to-bharat-biotech.html](http://www.hillemanlabs.org/resources/news/hilleman-laboratories-licenses-oral-cholera-vaccine-hillchol-to-bharat-biotech.html)



## A new Measles-Rubella vaccine prequalified by WHO: Another affordable option for vaccine supply

**Geneva, 29<sup>th</sup> September 2019** – A new measles-rubella (MR) vaccine has been prequalified by the World Health Organization (WHO) from Biological E (BioE), in partnership with PATH. Like measles, rubella is known for the long-term health consequences it can wreak on children less than five years old. Given the high risk of death or debilitating complications malnourished children face, the WHO recommends tackling these illnesses together, with the MR vaccine. Unfortunately, adequate supply is a challenge.

Securing robust and affordable MR vaccine supply is critical: few diseases are more contagious than measles, and few public health interventions have had such a dramatic and rapid impact as the introduction of the measles vaccine. WHO prequalification allows a vaccine to be procured through common subsidized funding mechanisms like Gavi, the Vaccine Alliance, and/or UNICEF. It means a vaccine has achieved WHO’s standards for manufacturing, safety, and ef-

ficacy, and it is the result of a vaccine's development journey that is several years in the making.

PATH partnered with BioE beginning at the research and development phase, and provided technical assistance and expertise to improve BioE's manufacturing process and increase its production capacity. Eventually, PATH provided input into the design of a new facility dedicated solely to MR vaccine production to ensure a robust supply and supported BioE through the process of WHO prequalification. PATH's Center for Vaccine Innovation and Access and BioE are guided by principles of accessibility and affordability for the communities who most need vaccines.

More information at: [path.org/articles/new-measles-rubella-vaccine-those-who-need-it-most/](http://path.org/articles/new-measles-rubella-vaccine-those-who-need-it-most/)



## Approval from the World Health Organization to help more countries access protection against pneumonia

**Pune, 18<sup>th</sup> December 2019** – There's reason to celebrate the pneumococcal vaccine that has recently been WHO-prequalified and will be made available to low- and middle-income countries. In 2008, Serum Institute of India, Pvt., Ltd. and PATH started a collaboration with support from the Bill & Melinda Gates Foundation to develop a pneumococcal vaccine that provides the protection that children in these settings need and breaks down barriers to access. Each year, nearly 400,000 children under five years of age die from pneumococcal disease globally, mostly in Africa and Asia. WHO prequalification opens the door for this new vaccine, PNEUMOSIL®, to bolster the prevention and save more lives by enabling access that countries in these regions can afford and sustain long term.

Prior to partnering on PNEUMOSIL®, Serum Institute and PATH had already worked together with other partners on another high-quality, low-priced conjugate vaccine against meningitis A-MenAfriVac®. Developed upon request from health ministers in Africa's meningitis belt, the vaccine has es-

entially wiped out meningitis A disease in affected countries. It also enabled to optimize efficient conjugate vaccine manufacturing processes applied to bring PNEUMOSIL®'s combined with appropriate serotypes helped minimize cost. PNEUMOSIL® includes the 10 likeliest serotypes that sicken and kill children in Africa, Asia, and Latin America.

More information at:

[www.seruminstitute.com/news\\_pneumococcal\\_vaccine.php](http://www.seruminstitute.com/news_pneumococcal_vaccine.php)



## Sinovac Biotech received approval for its varicella vaccine

**Beijing, 27<sup>th</sup> December 2019** – The China National Medical Products Administration (NMPA) has approved and issued a Product license for Sinovac's varicella vaccine to prevent the varicella-zoster virus in children from 1 to 12 years old. Varicella, commonly known as "chickenpox," is a highly contagious infectious disease caused by the varicella-zoster virus. The disease is spread by direct contact or through respiratory droplets. It is characterized by the appearance on the skin and mucous membranes of successive crops of lesions that are easily broken and become scabbed. Varicella usually affects children and is relatively benign, but complications may arise in the form of pneumonia and encephalitis. After infection, the virus may be reactivated and develop into herpes zoster, commonly known as "shingles," in older adults.

Mr. Weidong Yin, Chairman, President and CEO of Sinovac, commented, "The approval of our varicella vaccine allows us to provide another high-quality product to address unmet medical needs for the Chinese population. Moreover, with approximately 40 countries including varicella vaccines in their government sponsored national immunization programs, we have a positive outlook in our ability to provide varicella vaccines to markets outside of China and generate additional sources of growth."

More information: [www.businesswire.com/news/home/20191227005157/en/Sinovac-Announces-Approval-Varicella-Vaccine-Prevention-Varicella-Zoster](http://www.businesswire.com/news/home/20191227005157/en/Sinovac-Announces-Approval-Varicella-Vaccine-Prevention-Varicella-Zoster)

# Training opportunities to Master Vaccines Faster

The training initiative continued to offer interactive workshops, and e-learning opportunities. It is also pursuing development of virtual reality “hands-on” experience. DCVMN training workshops have three distinct learning phases: (i) preparation, (ii) workshop participation and (iii) knowledge dissemination. Participants are asked to prepare through e-learning courses. The face-to-face event enables interactive discussions. Subsequently, further content mastery and knowledge dissemination is encouraged by asking the participant to train colleagues within their company.



**48 TRAINING WORKSHOPS**

- 1) E-learning Preparation courses
- 2) Face to Face workshop & Interactive Discussion
- 3) Train the Trainer

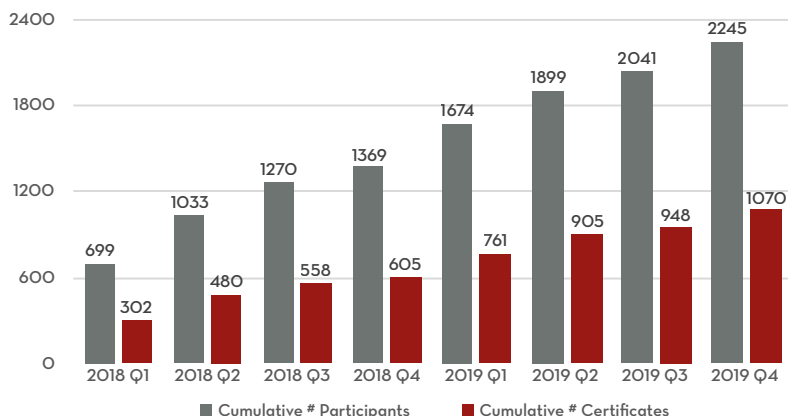
**12 E-LEARNING COURSES**

- Learning for All
- Self-tutorial
- Free & Easy Access
- Website at moodle.dcvmn.net
- Immersive Learning (hands-on)
- Easy Access
- Realistic Scenarios
- Safe & Controlled Exercises

Credit: Key Facts & Figures, designed by E.J.Hur based on data accrued by DCVMN since 2013.

DCVMN launched its e-learning platform for members in December 2016 offering free, self-paced learning with easy access from anywhere in the world at any time. E-learning courses are in the form of slideshow presentations and provide a final evaluation quiz. Once participants score at least 80%, a customized certificate can be downloaded immediately. From inception to the end of 2019, 2,245 participants enrolled in e-learning courses, and

1,070 certificates were delivered. Four new courses were launched in 2019, bringing the total to 12. There were 876 participants in 2019, and 465 certificates were issued regularly throughout the year. This represents an increase of 64 and 77% points, respectively, from the cumulative total from 2016 to 2018 (see figure above). It is anticipated that new courses will drive even higher engagement with the e-learning platform in 2020.



DCVMN E-learning courses available online and cumulative number of participants per course in 2018 and 2019.



In 2019, five regional training workshops were held in China, Singapore, Brazil, India and Vietnam, with 261 participants, from 31 companies and 12 countries, in total. The average age of participants is 37, which sug-

gests that most participants are mid-career professionals and therefore the knowledge gained is likely provide benefit over the long-term. A balanced gender attendance is also noted (55% female & 45% male).

Date	Topic	Location	Number of participants	Average age	Gender balance (F/M)
21-25 Jan 2019	Vaccines' Supply Chain Best Practices, Traceability and Evaluation	Shenzhen, China	49	35	47% / 53%
27-28 March 2019	Common Technical Document (CTD)	Singapore, Singapore	52	36	70% / 30%
27-30 May 2019	Vaccine Safety Monitoring and Pharmacovigilance	Sao Paulo, Brazil	38	40	69% / 31%
10-13 June 2019	Chemistry Manufacturing and Controls fostering implementation of vaccine release test methods aimed at reducing animal use	Hyderabad, India	72	37	40% / 60%
25-28 Nov 2019	Quality by Design and supply chain modelling	Hanoi, Vietnam	50	39	48% / 52%
<b>TOTAL</b>			<b>261</b>	<b>37</b>	<b>55% / 45%</b>

**Table 1.** DCVMN Training workshops in 2019. These efforts were partly supported by a grant from the Bill and Melinda Gates Foundation (grant OPP I2O4376)



Vaccines' Supply Chain Best Practices, Traceability and Evaluation workshop, 21-25<sup>th</sup> January 2019, Shenzhen, China.





*Supply Chain and QbD training workshop, 25-28<sup>th</sup> November 2019, Hanoi, Vietnam.*



*Regulatory Working Group, 25-26<sup>th</sup> March 2019, Singapore.*



*Pharmacovigilance workshop, 27-30<sup>th</sup> May 2019, Sao Paulo, Brazil.*



*CMC workshop 10-13<sup>th</sup> June 2019, Hyderabad, India.*



*Reduce, refine, replace (3Rs) initiative, Working Group meeting, 2<sup>nd</sup> December 2019, Bangkok, Thailand.*



# Best practices sharing working groups:

## Regulatory, Pharmacovigilance & Supply chain

In 2018, DCVMN was tasked with the strategic goal of seeking solutions, jointly with manufacturers, for enabling the stable, sustainable supply of high quality vaccines to developing countries to increase global immunization.

Sharing best practices is an effective way to improve performance across organizations. Theoretically, best practices must be identified, recognized and then rolled out within each company, to raise every employee's awareness and drive continuous improvement. Best practices sharing also enable benchmarking, the practice of comparing business processes and performance metrics to industry "best" companies and their practices. Dimensions typically measured are quality, time and cost.

Since 2015, DCVMN has invested significant resources in identifying areas of common interest where industry members are seeking support for improving vaccine supply. In this context, a regulatory working group was formed with voluntary participation of DCVMN members and IFPMA members. Challenges and opportunities for improving access to vaccines in emerging countries through efficient and aligned registration procedures were shared.<sup>1</sup>

An external survey conducted in 2018, and subsequent surveys designed by independent experts, have identified topics of common interest to DCVMN members in regulatory science, pharmacovigilance and vaccine supply as priorities for the growth of the vaccine industry. Thus, two new working groups for best practices sharing were launched in 2019: supply chain efficiency and pharmacovigilance for vaccines safety monitoring. Furthermore a third new working group on 3Rs<sup>2</sup> was formed (see page X), related to regulatory QC testing and lot release. There are, therefore, four DCVMN working groups on best practice currently in operation.

In 2019, a survey was conducted to understand the existing pharmacovigilance structures, practices and expertise of vaccine companies from emerging country manufacturers: 34 of the 43 contacted companies participated voluntarily and the results served as the basis to design an action plan to improve pharmacovigilance systems. Similarly, a survey on supply chain practices among DCVMN members was conducted and views gathered from 26 respondents served as the basis to prioritize topics and design a roadmap to improve supply efficiencies.



### Opportunities for improving access to vaccines in emerging countries through efficient and aligned registration procedures: An industry perspective<sup>☆</sup>

<sup>1</sup> *Opportunities for improving access to vaccines in emerging countries through efficient and aligned registration procedures: An industry perspective*. Dellepiane N, Pagliusi S; Regulatory Experts Working Group. *Vaccine*. 2019 May 21;37(23):2982-2989. doi: 10.1016/j.vaccine.2019.03.025.

<sup>2</sup> <https://www.nc3rs.org.uk/the-3rs>



membership to



In 2018 and 2019, DCVMN organized discussions with member manufacturers around technical advancements supporting a move towards in vitro alternatives to animal testing.<sup>3</sup> Based on those discussions, together with the Istituto Superiori di Sanita Italy (<https://www.iss.it/>) and INTRAVACC (<https://www.intravacc.nl/>), DCVMN developed a concept paper on the “In-house validation of the Pertussis Serological Potency Test (PSPT) in mice to replace the in vivo challenge Mouse Protection Test in whole-cell Pertussis (wP) vaccine batch testing”, that was presented to the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and eventually elaborated as a proposal for funding against NIIMBL Project Call 3.1G opportunity. It was proposed to create a consortium of ten laboratories, including six vaccine manufacturers and three national control laboratories plus INTRAVACC, to pursue the validation study over 18 months. This project is under the governance of a DCVMN working group dedicated to the 3Rs (replacement, refinement, reduction). The 3Rs is a framework for fostering more humane R&D ([www.nc3rs.org.uk/the-3rs](http://www.nc3rs.org.uk/the-3rs)). This project represents a new area of activity, where DCVMN International engages with NIIMBL as a non-profit member (cf. <https://niimbl.force.com/s/membership-information>).

Briefly, the NIIMBL Global Health Fund (GHF) was established by NIIMBL with funding contributed by the Bill & Melinda Gates Foundation (BMGF) to develop and implement innovative technologies for vaccine and biological manufacturing that will accelerate development timelines, lower the cost of manufacturing, secure supply for GAVI, the Glo-

bal Alliance for Vaccines and Immunization, and to ensure appropriate product profiles for their geographies, all in furtherance of BMGF’s charitable objectives (the “Purpose”). To advance the Purpose, BMGF conducted a survey of the members of the Developing Country Vaccine Manufacturers Network (DCVMN) to identify topics that were of greatest interest.<sup>4</sup> The survey revealed that 100% of respondents were interested in the development of alternative in vitro assays to reduce the reliance on animal testing required for lot release. Key issues for the DCVMN associated with animal testing include: variability across labs, supply of animal, lack of trained operators, environmental variants and differences in requirements among pertinent regulatory bodies, and the fact that the studies themselves are generally expensive and time consuming. The award (if made) will be controlled, made and managed solely by NIIMBL.

On 02<sup>nd</sup> December 2019, eleven DCVMN members agreed to have representatives to form a DCVMN 3Rs Working Group (WG). The objectives of the WG are:

- the improvement on the expertise on novel technologies that could be applied to reduce, refine and replace (3Rs) animal testing;
- the support in the implementation and the harmonisation of non-animal based approaches in vaccines manufacturing and release.

Initially, the WG has agreed to focus discussion on Diphtheria-Tetanus-Pertussis containing vaccines, rabies vaccines and on the alternative to the rabbit pyrogenicity test.

<sup>3</sup> (cf. <https://www.dcvmn.org/Chemistry-Manufacturing-and-Controls-fostering-implementation-of-vaccine> ; <https://www.dcvmn.org/Regional-workshop-Optimization-of-vaccines-manufacturing-containers-and-testing>

<sup>4</sup> More information at : <https://niimbl.force.com/s/4-18-19-Global-Health-Fund-Workshop>

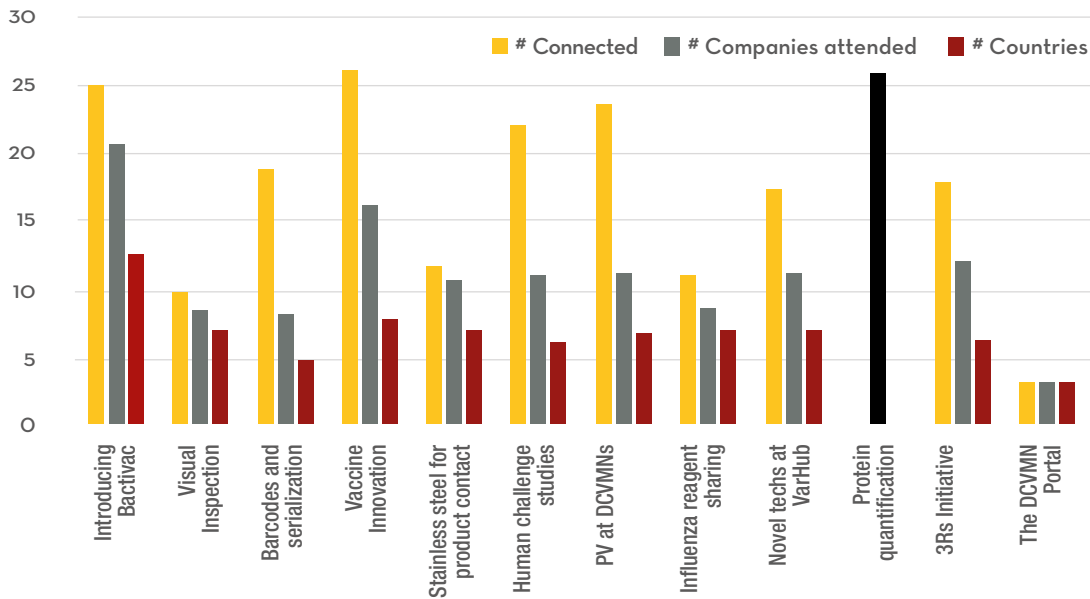
# Nurturing access to expertise and technical capabilities

DCVMN seeks to promote open and equitable access to knowledge and information to all members through online platforms. These include DCVMN-hosted webinars and the website “DCVMN Portal”, which presents two databases: available consultants and technical collaboration possibilities.

Webinars, presented voluntarily by experts from resource member or partner organizations on industry developments and technical topics, have been offered approximately monthly since 2015. They continue to be a useful platform for regular contact with members.

The first database assembles information on professional consultants with regional or international experience who voluntarily registered, and are available to provide ad hoc support to members facing capacity needs. The second database lists spare technical capacities and capabilities that member companies voluntarily wish to make available to other members, such as filling capacity for different containers types or packaging capabilities.

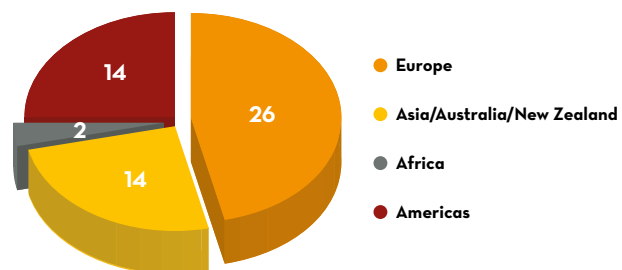
These might be needed in surge periods, such as outbreaks or seasonal peaks, or can facilitate accelerated access to vaccines in various presentations through leveraging established capacities elsewhere.



Number of connections, companies and countries at DCVMN webinars in 2019, Black Column indicates the number of downloads for this recorded October webinar, accessible at <https://www.dcvmn.org/-Webinar-materials-13->



Regional distribution of consultants available on the Portal



DCVMN Portal available at [www.dcvmn.org](http://www.dcvmn.org) and regional distribution of available consultants.

# 20<sup>th</sup> Annual General Meeting

Research and Development as the answer  
to vaccine shortages and low coverage



Opening speech by the Brazilian Minister of Health, Luiz Henrique Mandetta.

**Rio de Janeiro, 22<sup>nd</sup> October 2019** – The Brazilian Minister of Health, Luiz Henrique Mandetta, addressed the delegates at the 20<sup>th</sup> DCVMN Annual General Meeting, affirming that vaccines represent a global public good, as their benefits are universal across countries, people and generations. He mentioned the challenges imposed by the re-emergence of vaccine preventable diseases, due to low vaccination coverage, shortages of vaccines, vaccine hesitancy, anti-vaccination lobbying and the spreading of disinformation.

Recognizing the need to invest in research and development for vaccines in a sustainable manner, the Ministry of Health intends to support national production capacity by expanding the facilities of Bio-Manguinhos and Butantan Institute through public-private financing. The development of dengue vaccines by Butantan Institute and schistosomiasis, leishmaniasis, Zika and meningitis C vaccines by Fiocruz and the validation of vaccine candi-

dates against leprosy, tuberculosis and chikungunya, among others, illustrate ongoing international partnerships.

The presentations and panels of experts discussed the innovations needed to scale-up access to vaccines in the following areas:

- Innovations for immunization
- Procurement & financing of vaccines
- Public market dynamics
- Access to capital for innovation
- Innovative partnerships
- Regulatory convergence for safety
- Market intelligence
- Vaccine Innovation Prioritization Strategy (VIPS)
- Future vaccines and innovative technologies



# Opening speeches by public health officials



*From left to right: Minister Mandetta, Dr. N. T. Lima, President of Fiocruz Foundation, Dr. M. Zuma, Director of Biomanguinhos*



*Speech by PAHO Director, Dr. C. Etienne*



*Delegates at the audience*



*Minister Mandetta, M. Zuma and E. Kadilli, UNICEF*



*Prof. Dimas, (standing) greeting Minister Mandetta (left), PAHO Assistant Director J. Barbosa (middle) and Dr. A. Homma*



*Welcome words by Biomanguinhos director, M. Zuma*



*M. Datla, DCVMN President, S. Pagliusi, DCVMN Executive Secretary, N.T. Lima, Fiocruz President and Minister Mandetta*



# Plenary discussions on Innovation for immunization



K. O'Brien, WHO



R. Donis, BARDA



D. Kaslow, CVIA, PATH



S. Missailidis, Biomanguinhos



F. Kristensen, CEPI

# Plenary discussions on Procurement, Financing & Public markets



*J. Fitsimmons, PAHO Revolving Fund*



*E. Kadilli, UNICEF SD*



*S. Berkley, GAVI*



*Y. Kim, RIGHT fund*



*R. Prasad, Gates Foundation*



*A. Wartel, IVI*



*S. Prasad, Bharat Biotech*



# Open dialogue on Regulatory convergence



*H. Rodriguez, WHO*



*B. Moreira, ANVISA*



*N. Dellepiane, DCVMN*



*D. Maiga, WHO AVAREF*



*A. Guta, PAHO*



*S. Desai, Zydus Cadila*

# Innovative Corporate Partnerships



*H. Jain, R. Suri, A. Homma and S. Jadhav.*



*M. Lundgren, T. Prussik, T. Kram.*

## Panel discussions: Leveraging Public markets & Global demand



*D. Hein, Gavi*



*A. Ottosen, UNICEF*



*Y. Momeni, UNICEF*



*A. Wong, Walvax*



*S. Jadhav, SII*



*T. Cernuschi, WHO*



*P. Tippoo, Biovac*



*E. Baker, Gavi*



## Sharing knowledge on future vaccines for Responsible innovation



*Q. Zhang, Minhai Biotechnology*



*B. Pierce, Imperial College London*



*A. Precioso, Butantan Institute*



*R. Ella, Bharat Biotechnology*



*M. Menozi-Arnaud, Gavi, and D. Kristensen PATH*



*Prof. S. Gilbert, Oxford University and L. Yang, CNBG*



*J. Cuccui, C. López Macías, B. Pierce, C. MacLennan, D. Dat*



*M. Zuma with delegates during the event*



## Closing statements



A. Homma, Bio-Manguinhos/Fiocruz, concluded the meeting and thanked the large number of people who contributed to open and productive deliberations, updating manufacturers on current thinking in strategy, innovation, planning and operational areas. Strategic topics covered WHO's IA2030 strategy, evaluation of coverage gaps and inequi-

ties by Gavi and others, identification of new market trends for the decade ahead and promotion of a holistic system view of needs, costs and benefits. He urged DCVMs to accelerate innovation and pre-qualify their products to strengthen vaccination as a global good.



*Bio-Manguinhos team*

## Governance statements

In 2018, following a study by a strategic consulting firm, the Executive Committee recommended a restructure of the Network governance functions, delegating the day-to-day operational approvals to committees, working groups and secretariat senior staff. In this new configuration, the Executive Committee takes the role of a “governing board”, focusing on engagement with international bodies, fundraising for sustainability of the Network activities, strategic planning, overseeing and approving (or not) the recommendations of the various committees/working groups.

Consequently, the Executive Committee in 2019 was transitioning to function as a governing board, focusing on key strategic decisions, holding 4-5 meetings or TCs annually, as compared to 10-11 previously. In 2019 records from EC meetings or teleconferences are available for 20<sup>th</sup> February, 1<sup>st</sup> April, 14<sup>th</sup> May, 21<sup>st</sup> October and on 11<sup>th</sup> December. All EC members act on a voluntary, non-remunerated basis. Three teleconferences (TC) and two face-to-face meetings were held in 2019, with pre-set agenda items and relevant documents circulated in advance to facilitate informed decisions (see table below).

Role	Name	Company	Attendance out of 5 TC/or meetings
President and Gavi Alternate	Ms. Mahima Datla	Biological E	2
Vice-President	Dr. Alexander Precioso	Butantan	4
Treasurer	Mr. Fernando Lobos	Sinergium	4
Member	Mr. Steven Gao	Innovax	5
Member	Ms. Lingjang Yang	CNBG-Sinopharm	5
Member	Mr. Patrick Tippoo	Biovac	5
Member and Gavi Board representative	Mr. Sai Prasad	Bharat Biotech	3
EC Senior Adviser (non-voting)	Dr. Akira Homma	Biomanguinhos	3
EC Senior Adviser (non-voting)	Dr. Suresh Jadhav	Serum Institute of India	4
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	5

**Table 2.** Governance meetings

In 2019, Secretariat embraced the recommendations by expanding the Donors Advisory Committee (AC) to include representatives from Imperial College London and PATH, together with the Gates Foundation and four DCVMN corporate member representatives, who voluntarily expressed interest

and availability to support Network governance functions. The Advisory Committee meetings or TCs were also held 4-5 times annually, guiding many of the day-to-day activities. In addition, expert Working Groups (WGs,) formed around four strategic areas (supply chain, regulatory affairs, 3Rs and vac-

cine safety/pharmacovigilance) support the Advisory Committee in the daily operational decisions. WG meetings or TCs are held ad hoc, but regularly, to advance the respective projects of common interest to most members. AC and WG members act on a voluntary non-remunerated basis, similar to EC members. Each WG, includes about ten representatives from member companies, with expertise in the respective subject matter, steering the related activities. They are currently supported by four senior expert consultants, who help develop and analyse surveys, draft white papers and presentations, report

on projects, support training & communication materials, etc. This new structure empowers the members to be directly involved in leading and directing the future activities.

In addition, to strengthen the above-mentioned leadership structure and implement the tasks and activities recommended by the governing board and the advisory committee, secretariat positions were opened for a Chief Strategy Officer (100% FTE), a project manager (25% FTE), a training manager (50% FTE) and a research associate (40% FTE).

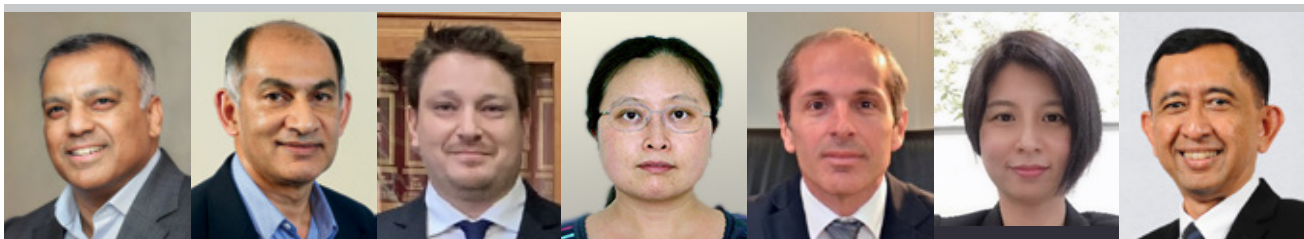
## DCVMN International welcomes newly formed Executive Committee 2020-23

At the General Assembly held on 21<sup>st</sup> October 2019, the Executive Committee proposed amendments to the DCVMN International bylaws. The objectives were clarification and alignment with current practices, already implemented but not yet documented, minimizing redundancies due to the historical nature of the bylaws. These were set 20 years ago, reviewed almost ten years ago, so needed amendments to reflect the modern governance practices. As a first step, proposed amendments to articles 3.2., 3.5., 3.9, 3.11, 4.1., 8.8., 9.1. and 9.4. were approved by the assembly, with no objections voiced.

Elections for Executive Committee members were held on 22<sup>nd</sup> October 2019, according to the article

3.9 and of the bylaws/internal rules. The candidates gaining the most votes formed the new elected Executive Committee 2020-2022, composed as follows:

- Sai Prasad, President
- Patrick Tippoo, Vice President
- Tiago Rocca, Executive Committee member
- Adriansjah Azhari, Executive Committee member
- Fernando Lobos, Executive Committee member
- Lingjiang Yang, Executive Committee member
- Weidan (Wendy) Huang, Executive Committee member



The Committee brings together a range of skills and experiences to represent corporate members around the globe, in governing an organization, sharing the commitment to contribute to improving vaccination for all people, through their involvement

amidst meetings, events, committees, activities, and special projects. Sai Prasad is the President to the Committee for the coming period and new EC members are Tiago Rocca, Adriansjah Azhari and Wendy Huang.



# Financial statements

The accounts of 31<sup>st</sup> December 2019 showed liquidities of 3'128'561.88 USD available to DCVMN International at the bank in Switzerland. It is noted that the funds from donors are kept in separate accounts and are dedicated for use only for purposes/activities agreed by the donors in accordance with signed agreements, and not used to support unrelated activities or staff fringe benefits. Membership/partnership funds are used for

secretariat maintenance costs including staff salaries, fringe benefits, insurances and administrative supplies/support, as well as for the organization of the AGM and some training activities. Secretariat expenses are aligned with the 5-year strategic plan.

Membership status as of December 2019 indicated that there were 43 members, of which 15 were full members (with WHO PQed vaccines). In 2019, three members did not settle membership contributions.

## BALANCE SHEET AS AT 31 DECEMBER

ASSETS	31.12.2019		31.12.2018	
	CHF	USD	CHF	USD
<b>Current assets</b>				
Liquidities	3'029'699.33	3'128'561'88	1'652'639.93	1'676'445.46
Investments	0.00	0.00	295'965.62	300'228.87
Advance deposit for expenses	4'842.00	5'000.00	4'929.00	5'000.00
Members contribution to receive	49'388.40	51'000.00	29'574.00	30'000.00
Provision for loss on members contributions	-37'767.60	-39'000.00	-29'574.00	-30'000.00
Regus deposit	58.00	59.89	58.00	58.84
Prepaid expenses	5'164.63	5'333.16	3'398.62	3'447.58
<b>Total current assets</b>	<b>3'051'384.76</b>	<b>3'150'954.93</b>	<b>1'956'991.17</b>	<b>1'985'180.75</b>
<b>TOTAL ASSETS</b>	<b>3'051'384.76</b>	<b>3'150'954.93</b>	<b>1'956'991.17</b>	<b>1'985'180.75</b>
<b>LIABILITIES</b>	<b>CHF</b>	<b>USD</b>	<b>CHF</b>	<b>USD</b>
<b>Short-term liabilities</b>				
Payables	31'236.61	32'255.91	5'716.29	5'798.66
Donations carryover to 2020	448'605.49	463'244.00	0.00	0.00
Accrued expenses	278'915.63	288'016.97	27'545.80	27'942.59
<b>Total short-term liabilities</b>	<b>758'757.73</b>	<b>783'516.88</b>	<b>33'262.09</b>	<b>33'741.25</b>
<b>Unrestricted reserves</b>				
Capital	1'923'729.08	2'031'975.60	1'859'548.74	1'963'653.19
Translation adjustment USD/CHF		5'232.42		-80'536.10
Net result for the year	368'897.95	330'230.03	64'180.34	68'322.41
<b>Total unrestricted reserves</b>	<b>2'292'627.03</b>	<b>2'367'438.05</b>	<b>1'923'729.08</b>	<b>1'951'439.50</b>
<b>TOTAL LIABILITIES</b>	<b>3'051'384.76</b>	<b>3'150'954.93</b>	<b>1'956'991.17</b>	<b>1'985'180.75</b>

## INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER

	2019		2018	
	CHF	USD	CHF	USD
<b>Income</b>				
Members contributions	562'531.75	561'000.00	322'961.43	330'000.00
Provision for loss on members contributions	-37'767.60	-39'000.00	-29'574.00	-30'000.00
Reversal provision for loss on members contributions	29'574.00	30'000.00	19'490.00	20'000.00
Loss on members contributions	-29'574.00	-30'000.00	-24'362.50	-25'000.00
Donations received	1'331'092.30	1'324'915.86	700'264.70	702'000.00
Donations carryover to 2020	-448'605.49	-463'244.00	0.00	0.00
Annual meeting participants' contribution	32'875.55	32'820.00	39'383.86	39'740.00
<b>Total income before financial income</b>	<b>1'440'126.51</b>	<b>1'416'491.86</b>	<b>1'028'163.49</b>	<b>1'036'740.00</b>
<b>Other financial income</b>				
Income on investments	0.00	0.00	1'635.25	1'697.66
Gain on investments	16'005.18	16'048.51	0.00	0.00
Foreign exchange gain	0.00	0.00	24'735.00	22'417.31
<b>Total other financial income</b>	<b>16'005.18</b>	<b>16'048.51</b>	<b>26'370.25</b>	<b>24'114.97</b>
<b>TOTAL INCOME</b>	<b>1'456'131.69</b>	<b>1'432'540.37</b>	<b>1'054'533.74</b>	<b>1'060'854.97</b>
<b>Operating expenses</b>				
Mock audit Initiative	0.00	0.00	-103'344.83	-104'339.12
Best practice supply WG	-46'660.10	-46'884.78	0.00	0.00
Training Initiative	-157'243.45	-156'927.33	-74'693.01	-76'458.45
Regulatory Forum Initiative	-52'778.52	-52'612.59	-41'282.30	-41'374.76
Consulting Databases Initiative	-12'349.39	-12'410.41	-7'431.30	-7'501.74
Pharmacovigilance Initiative	-30'437.33	-30'558.99	0.00	0.00
Annual General Meeting	-69'147.22	-68'489.34	-60'057.01	-60'040.01
<b>Total operating expenses</b>	<b>-368'556.01</b>	<b>-367'883.44</b>	<b>-286'808.45</b>	<b>-289'714.08</b>
<b>Staff costs</b>				
Salaries	-177'224.00	-176'573.77	-137'792.00	-139'039.99
Social contributions AVS/AI/APG/AC/PCFam	-16'025.80	-15'915.54	-11'889.15	-11'720.29
Social and accident insurances	-3'592.30	-3'637.94	-2'746.85	-2'865.68
LPP contribution	-13'781.80	-13'815.80	-12'133.45	-12'323.27
<b>Total staff costs</b>	<b>-210'623.90</b>	<b>-209'943.05</b>	<b>-164'561.45</b>	<b>-165'949.23</b>
<b>Other operating expenses</b>				
Office rental	-7'211.63	-7'190.24	-7'211.64	-7'310.91
Office insurance	-350.25	-355.30	-389.10	-390.35
Office supplies	-4'012.20	-4'009.21	-2'940.81	-2'997.62
Accounting services	-12'153.95	-12'274.80	-15'368.85	-15'657.63
Legal consulting	-30'739.95	-31'726.09	-39'248.40	-40'129.16
HR and payroll services	-11'728.00	-11'665.17	-6'350.00	-6'294.80
Strategy professional services	0.00	0.00	-409'860.00	-405'000.00
Technical consulting sponsored by Imperial College	-54'913.58	-54'567.71	0.00	0.00
Financial audit	-10'433.00	-10'749.61	-2'371.25	-2'401.77
Publications	-2'584.80	-2'555.41	-2'805.60	-2'806.83
Travel and foreign expenses secretariat	-22'416.59	-22'361.13	-13'175.32	-13'500.09
Representation expenses	-3'533.32	-3'519.32	-3'085.12	-3'142.48
Executive Committee Meetings	-1'720.00	-1'751.28	-7'004.00	-7'199.16
Miscellaneous	0.00	0.00	-150.00	-150.03
<b>Total other operating expenses</b>	<b>-161'797.27</b>	<b>-162'725.27</b>	<b>-504'245.09</b>	<b>-501'315.51</b>
<b>EARNING BEFORE INTEREST AND TAXES</b>	<b>715'154.51</b>	<b>691'988.61</b>	<b>98'918.75</b>	<b>103'876.15</b>
<b>Financial expenses</b>				
Interest paid	-1.30	-1.34	-2.80	-3.00
Bank and PayPal charges	-3'391.62	-3'397.86	-3'674.43	-3'750.69
Foreign exchange loss	-82'402.97	-89'659.15	0.00	0.00
Loss on investments	0.00	0.00	-18'785.78	-19'208.36
<b>Total financial expenses</b>	<b>-85'795.89</b>	<b>-93'058.35</b>	<b>-22'463.01</b>	<b>-22'962.05</b>
<b>EARNING BEFORE TAXES</b>	<b>629'358.62</b>	<b>598'930.26</b>	<b>76'455.74</b>	<b>80'914.10</b>
<b>Prior-period income and expenses</b>				
Prior year grant adjustment	-244'987.77	-252'982.00	0.00	0.00
Taxes on previous year	-333.90	-204.54	618'35	785'59
<b>Total prior-period income and expenses</b>	<b>-244'653.87</b>	<b>-252'777.46</b>	<b>618.35</b>	<b>785.59</b>
<b>RESULT BEFORE TAXES</b>	<b>384'704.75</b>	<b>346'152.80</b>	<b>77'074.09</b>	<b>81'699.69</b>
Taxes	-15'806.80	-15'922.77	-12'893.75	-13'377.28
<b>NET RESULT FOR THE YEAR</b>	<b>368'897.95</b>	<b>330'230.03</b>	<b>64'180.34</b>	<b>68,322.41</b>

## Notes to the financial statements

### 1. Overview

#### Purpose of the association

DCVMN is a public health driven, international alliance of manufacturers, working to strengthen vaccine manufacturers through the provision of information and professional training programs, technology improvements, innovative vaccine research and development, encouraging technology transfer initiatives, and educating the public about the availability of safe, effective and affordable vaccines for all people.

### 2. Accounting principles applied in the preparation of the financial statements

These financial statements have been prepared in accordance with the statutes and the provisions of commercial accounting as set out in the Swiss Code of Obligations (Art. 957 to 963b CO).

#### Foreign currency translation

Assets and liabilities in foreign currencies are translated into Swiss francs at the exchange rate in effect at the balance sheet date. Transactions in foreign currencies are translated into Swiss francs at the rate in effect at the average monthly rate.

#### Liquidities

Cash and cash equivalents are carried in the balance sheet at their nominal value.

#### Investments

Investments are valued at market price, if any.

#### Contributions receivables

Members contributions to receive are carried at their nominal value. Charges are calculated for these assets on an individual basis.

#### Payables

Payables are recorded in the balance sheet at their nominal value on the basis of invoices corresponding to services made on the date of closing.

#### Recognition of revenues and expenses

Revenues are recorded on the principle of periodicity, i.e., when revenue-generating transactions or events occur rather than on the basis of cash flows.

Expenses are recorded according to the principle of periodic delimitation, i.e. when the operations or events generating expenses occur and not according to cash flows.

### 3. Details, analyses and explanations to the financial statements

#### Number of full-time

The number of full-time employee equivalents did not exceed 10 on an annual average basis.

#### Pension liabilities

On 31 December 2019 the liability to the pension scheme amounted to CHF 4'383.10 / USD 4'526.13 (31 December 2018: CHF 3'291.70 / USD 3'339.12).

#### Explanations of extraordinary, non-recurring or prior-period items in the income and expenditure statement

##### • Donations carryover to 2020

The amount of CHF 448'605.49 / USD 463'244.- was unused by 31st December 2019 and therefore deferred as carryover to be disbursed in 2020, with agreement of the donor. Carryover is the process by which unobligated funds remaining at the end of a budget period may be carried forward to the next budget period to cover allowable costs in that budget period. The carryover of funds enables grantees to use unexpended prior year grant funds in the next budget period.

##### • Prior year grant adjustment

A negative adjustment in a philanthropic pledge resulted in a reduction of CHF 244'987.77 / USD 252'982.- in the 2019 financial statements.

#### Significant events occurring after the balance sheet date

On January 29, 2020, the World Health Organization declared the coronavirus that emerged at the end of 2019 as a public health emergency of international concern. The containment of the population has been decreed in Switzerland and in most countries, leading to a very sharp decrease in economic activity for a period of time that cannot be predicted. The result for the year 2020 will be strongly influenced by this situation.

No provision has been made in the financial statements for the year ended December 31, 2019 in connection with the uncertainties related to COVID-19.

### 4. General comments

1. DCVMN annual revenue from memberships, donations and financial gains in 2019 increased by 76%, to CHF 1'942'504.78 / USD 1'934'784.37 before carryover, and before the variation on the provision on members contributions, from CHF 1'088'980.24 / USD 1'095'854.97, in 2018.

2. The Executive Committee's proposed budget for 2020 targeted at 1'897'289 USD income and 1'608'000 USD for expenses, which was approved by the assembly of members on 21st October 2019, in Rio, Brazil.

3. The budget income for 2020, was based on the assumptions below:

- a philanthropic pledge of 758'289 USD, allocated for training and regulatory related activities in 2020.
- a pledge of ca. 300'000 GBP, allocated for QC, GMP and technology support in 2020.
- the membership contributions expected to remain similar to 2019; note that three members are in arrears and related losses were provisioned. The funds received from members are dedicated to administrative operations including secretariat, rental, IT, supplies communication and staff salaries.
- continuous corporate partnership contributions estimated at ca. 200'000 USD, for workshops and AGM. Fees to AGM non-members participants at around 20'000 USD.

Note that exchange rate volatility may influence the budget slightly up/downwards.

4. All income and disbursements are handled exclusively by bank transfers, providing traceable, independent and accurate accounting records, complying with international accounting and business practices. All disbursements are subject to a two-signature system approval, prepared by the Secretariat and approved by the Treasurer, with two witnesses, an external comptroller and a DCVMN member. All disbursements correspond to bank transaction records and invoices corresponding to services. Accounts are available to corporate members, nominated by the Executive Committee, as well as by donors and local authorities, for financial review and assessment.

5. Of note, in 2019 the USD/CHF exchange rate contributed to foreign exchange loss of CHF 82'402.97 / USD 89'659.15, reflecting the value of the dollar on 31 December 2019, against local currency (CHF) 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.

6. "Reversal of provision for loss on membership contributions" indicates the debt of membership payments for 2018-19, expected but not received.

7. The unaudited financial statements were prepared by Multifiduciaire Genève S.A., ([www.multigeneve.ch](http://www.multigeneve.ch)), under the oversight and responsibility of DCVMN Executive Committee, in February 2020, reviewed by an external audit firm (PwC) and modified in October 2020.



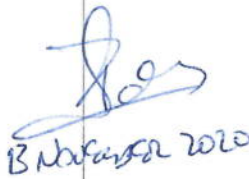
**DCVMN International**  
 Developing Countries Vaccine Manufacturers Network  
 CH-1260 Nyon

**BALANCE SHEET AS AT 31 DECEMBER**

<u>ASSETS</u>	<u>31.12.2019</u>		<u>31.12.2018</u>	
	<u>CHF</u>	<u>USD</u>	<u>CHF</u>	<u>USD</u>
<u>Current assets</u>				
Liquidities	3'029'699.33	0.9684 3'128'561.88	1'652'639.93	0.9858 1'676'445.46
Investments	0.00	0.0000 0.00	295'965.62	0.9858 300'228.87
Advance deposit for expenses	4'842.00	0.9684 5'000.00	4'929.00	0.9858 5'000.00
Members contributions to receive	49'388.40	0.9684 51'000.00	29'574.00	0.9858 30'000.00
Provision for loss on members contributions	-37'767.60	0.9684 -39'000.00	-29'574.00	0.9858 -30'000.00
Regus deposit	58.00	0.9684 59.89	58.00	0.9857 58.84
Prepaid expenses	5'164.63	0.9684 5'333.16	3'398.62	0.9858 3'447.58
<b>Total current assets</b>	<b>3'051'384.76</b>	<b>3'150'954.93</b>	<b>1'956'991.17</b>	<b>1'985'180.75</b>
<b>TOTAL ASSETS</b>	<b>3'051'384.76</b>	<b>3'150'954.93</b>	<b>1'956'991.17</b>	<b>1'985'180.75</b>
<u>LIABILITIES</u>				
<u>Short-term liabilities</u>				
Payables	31'236.61	0.9684 32'255.91	5'716.29	0.9858 5'798.66
Donations carryover to 2020	448'605.49	0.9684 463'244.00	0.00	0.0000 0.00
Accrued expenses	278'915.63	0.9684 288'016.97	27'545.80	0.9858 27'942.59
<b>Total short-term liabilities</b>	<b>758'757.73</b>	<b>783'516.88</b>	<b>33'262.09</b>	<b>33'741.25</b>
<u>Unrestricted reserves</u>				
Capital	1'923'729.08	2'031'975.60	1'859'548.74	1'963'653.19
Translation adjustment USD/CHF		5'232.42		-80'536.10
Net result for the year	368'897.95	330'230.03	64'180.34	68'322.41
<b>Total unrestricted reserves</b>	<b>2'292'627.03</b>	<b>2'367'438.05</b>	<b>1'923'729.08</b>	<b>1'951'439.50</b>
<b>TOTAL LIABILITIES AND RESERVES</b>	<b>3'051'384.76</b>	<b>3'150'954.93</b>	<b>1'956'991.17</b>	<b>1'985'180.75</b>



Hyderabad, India. 14Dec2020



B. Narasimha 2020



Nyon, 10 November 2020

**DCVMN International**  
Developing Countries Vaccine Manufacturers Network  
CH-1260 Nyon

**INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER**

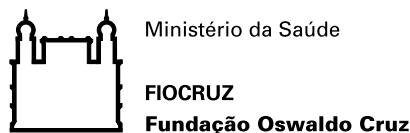
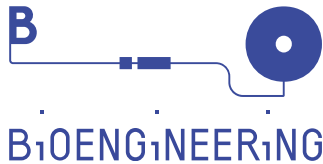
	2019		2018	
	CHF	USD	CHF	USD
<b>Income</b>				
Members contributions	562'531.75	561'000.00	322'961.43	330'000.00
Provision for loss on members contributions	-37'767.60	-39'000.00	-29'574.00	-30'000.00
Reversal provision for loss on members contributions	29'574.00	30'000.00	19'490.00	20'000.00
Loss on members contributions	-29'574.00	-30'000.00	-24'362.50	-25'000.00
Donations received	1'331'092.30	1'324'915.86	700'264.70	702'000.00
Donations carryover to 2020	-448'605.49	-463'244.00	0.00	0.00
Annual meeting contribution participants	32'875.55	32'820.00	39'383.86	39'740.00
<b>Total income before financial income</b>	<b>1'440'126.51</b>	<b>1'416'491.86</b>	<b>1'028'163.49</b>	<b>1'036'740.00</b>
<b>Other financial income</b>				
Income on investments	0.00	0.00	1'635.25	1'697.66
Gain on investments	16'005.18	16'048.51	0.00	0.00
Foreign exchange gain	0.00	0.00	24'735.00	22'417.31
<b>Total other financial income</b>	<b>16'005.18</b>	<b>16'048.51</b>	<b>26'370.25</b>	<b>24'114.97</b>
<b>Total income</b>	<b>1'456'131.69</b>	<b>1'432'540.37</b>	<b>1'054'533.74</b>	<b>1'060'854.97</b>
<b>Operating expenses</b>				
Mock audit Initiative	0.00	0.00	-103'344.83	-104'339.12
Best practice supply WG	-46'600.10	-46'884.78	0.00	0.00
Training Initiative	-157'243.45	-156'927.33	-74'693.01	-76'458.45
Regulatory Forum initiative	-52'778.52	-52'612.59	-41'282.30	-41'374.76
Consulting Databases initiative	-12'349.39	-12'410.41	-7'431.30	-7'501.74
Pharmacovigilance initiative	-30'437.33	-30'558.99	0.00	0.00
Annual General Meeting	-69'147.22	-68'489.34	-60'057.01	-60'040.01
<b>Total operating expenses</b>	<b>-368'556.01</b>	<b>-367'883.44</b>	<b>-286'808.45</b>	<b>-289'714.08</b>
<b>Staff costs</b>				
Salaries	-177'224.00	-176'573.77	-137'792.00	-139'039.99
Social contributions AVS/AI/APG/AC/PCFam	-16'025.80	-15'915.54	-11'889.15	-11'720.29
Social and accident insurances	-3'592.30	-3'637.94	-2'746.85	-2'865.68
LPP contribution	-13'781.80	-13'815.80	-12'133.45	-12'323.27
<b>Total staff costs</b>	<b>-210'623.90</b>	<b>-209'943.05</b>	<b>-164'561.45</b>	<b>-165'949.23</b>
<b>Other operating expenses</b>				
Office rental	-7'211.63	-7'190.24	-7'211.64	-7'310.91
Office insurance	-350.25	-355.30	-389.10	-390.35
Office supplies	-4'012.20	-4'009.21	-2'940.81	-2'997.62
Accounting services	-12'153.95	-12'274.80	-15'368.85	-15'657.63
Legal consulting	-30'739.95	-31'726.09	-39'248.40	-40'129.16
HR and payroll services	-11'728.00	-11'665.17	-635.00	-629.48
Strategy professional services	0.00	0.00	-409'860.00	-405'000.00
Technical consulting sponsored by Imperial College	-54'913.58	-54'567.71	0.00	0.00
Financial audit	-10'433.00	-10'749.61	-2'371.25	-2'401.77
Publications	-2'584.80	-2'555.41	-2'805.60	-2'806.83
Travel and foreign expenses secretariat	-22'416.59	-22'361.13	-13'175.32	-13'500.09
Representation expenses	-3'533.32	-3'519.32	-3'085.12	-3'142.48
Executive Committee Meetings	-1'720.00	-1'751.28	-7'004.00	-7'199.16
Miscellaneous	0.00	0.00	-150.00	-150.03
<b>Total other operating expenses</b>	<b>-161'797.27</b>	<b>-162'725.27</b>	<b>-504'245.09</b>	<b>-501'315.51</b>
<b>EARNINGS BEFORE INTEREST AND TAXES</b>	<b>715'154.51</b>	<b>691'988.61</b>	<b>98'918.75</b>	<b>103'876.15</b>
<b>Financial expenses</b>				
Interests paid	-1.30	-1.34	-2.80	-3.00
Bank and paypal charges	-3'391.62	-3'397.86	-3'674.43	-3'750.69
Foreign exchange loss	-82'402.97	-89'659.15	0.00	0.00
Loss on investments	0.00	0.00	-18'785.78	-19'208.36
<b>Total financial expenses</b>	<b>-85'795.89</b>	<b>-93'058.35</b>	<b>-22'463.01</b>	<b>-22'962.05</b>
<b>EARNINGS BEFORE TAXES</b>	<b>629'358.62</b>	<b>598'930.26</b>	<b>76'455.74</b>	<b>80'914.10</b>
<b>Prior-period income and expenses</b>				
Prior year grant adjustment	-244'987.77	-252'982.00	0.00	0.00
Taxes on previous year	333.90	204.54	618.35	785.59
<b>Total prior-period income and expenses</b>	<b>-244'653.87</b>	<b>-252'777.46</b>	<b>618.35</b>	<b>785.59</b>
<b>RESULT BEFORE TAXES</b>	<b>384'704.75</b>	<b>346'152.80</b>	<b>77'074.09</b>	<b>81'699.69</b>
Taxes	-15'806.80	-15'922.77	-12'893.75	-13'377.28
<b>NET RESULT FOR THE YEAR</b>	<b>368'897.95</b>	<b>330'230.03</b>	<b>64'180.34</b>	<b>68'322.41</b>

Hyderabad, India. 14Dec2020

Nyon 10 November 2020

# 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 2019 were hosted in partnership with DCVMN corporate partners here below:



We thank BioManguinhos and Fiocruz Foundation for hosting and supporting the 2019 annual general meeting, and the Bill and Melinda Gates Foundation for a grant to DCVMN (grant no. OPP1204376).





