

2022 ANNUAL REPORT

We Connect to Protect!



FOREWORD FROM DCVMN'S BOARD CHAIR

Dear DCVMN Members, Partners and Friends,

On behalf of DCVMN, I am happy to present to you the DCVMN Annual Report for 2022.

The past year has been a gradual return to normalcy, as we knew it before the pandemic. In the wake of this pandemic, we had the opportunity to assess our position as a network and plan for the future utilizing the knowledge we have gained.

Many believe that the network faced its biggest challenge of the 21st century. As my term as Board Chair winds down, I would like to take this opportunity to reflect on some of the key advancements made towards the strategic vision set out by the DCVMN board in 2020:

- The Network has now transitioned from an Executive Committee to a Board, and the Secretariat is now led by Mr. Rajinder Suri, the Network's first CEO.
- Additionally, we aimed to increase member involvement in several Working Groups (WGs). Over 100 personnel from member companies have been involved in Working Groups of the Secretariat (WGs). The WGs covered a variety of industry verticals, such as regulatory harmonization, clinical development, and product commercialization.
- Through representation at international conferences related to vaccines and public health, such as the WHO, CEPI, GAVI, ACT A group, WEF, and PAVM, we have begun advocating for a healthy and sustainable industry.
- By hiring new staff and subject matter experts, we were able to strengthen the secretariat. Our new personnel have been recruited from around the world, and not just from within the European continent.
- Our member companies supplied ~60% of COVID-19 vaccines globally. The network broke down barriers in various segments of the industry. Our accomplishments range from securing vaccine licenses at a rapid pace, to manufacturing and supplying volumes of life-saving vaccines that have never been tried before.

These advancements are not only a testament to the network's ability to commercialize vaccines, but also to its ability to grow expansively while fostering strong partnerships with industry stakeholders. As the growth of the network continues, keeping this growth sustainable and prioritizing a healthy industry should be the network's goal moving forward.

Beyond the accomplishments, I would like highlight the topics that were championed during the pandemic, which should be carefully evaluated, as we usher a new era for industry. Decentralized manufacturing and vaccine supply equity are critical. While there are more than 40 manufacturers in our network, only a few manufacturers were able to develop or manufacture a COVID-19 vaccine. We fell short in ensuring equitable access to COVID-19 vaccines globally. I was quite startled by this given that the network has extensive experience in providing non-pandemic essential vaccines in an equitable manner. The network boasts some of the largest vaccine suppliers in the world and offers over 80 different WHO-prequalified vaccines.

This discrepancy was in part due the lack of a consistent advance market commitment (AMC) allocation from industry stakeholders and equitable financial support for product development activities. Based on the feedback received from our member companies, in order to develop novel products and increase production capacities, I believe the network should encourage industry stakeholders to look a little closer at this discrepancy. Equitable product development financing and AMC allocation are necessary for equitable supply.

As I sign off, I would like to thank all members and partners of the network for entrusting me with this position, and wish the current Board elect the best of luck.

SAI D. PRASAD DCVMN Board Chair 1



MESSAGE FROM THE CEO

Honorable members, dignitaries and all stakeholders,

It gives me immense pleasure to present the 22nd Annual Report of DCVMN, 2nd in a row as the CEO of a strong network of 43 Developing Country Vaccine Manufacturers having diverse capabilities to innovate, develop, produce, and supply vaccines against dreaded diseases for domestic and global use. Especially now when we are in the 3rd year of the unprecedented COVID-19 pandemic, I can proudly say that DCVMN members collectively contributed to over 60% of the

global production and supply of COVID-19 vaccines of 11.3 billion doses to protect billions of people in LICs and LMICs, though the inequities in distribution especially in 2021 still haunt us compelling to take 'Vaccine Equity and Timely Access' as the take home message which we dutifully adopted as a theme to address during DCVMN's 23rd Annual General Meeting (AGM) held in Pune, India from October 20-22, 2022 inaugurated by Dr Mansukh Mandaviya, Honorable Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers, Government of India, bringing together the leadership of all global health and financial agencies, policy makers, regulators, scientists and industry stalwarts under one roof to debate and discuss the burning issues and help develop a roadmap in search of solutions. It is clear that a strong political will, pandemic accord and funding support are critical for sustainable vaccine manufacturing in LMICs. Building regional vaccine manufacturing capacity, especially in Africa is one of the most critical requirements in ending inequity which can be achieved through Southto-South collaborations. There's no second thought that innovation, technology transfers, multilateral trade agreements and trainings are key for sustainable vaccine equity in which DCVMN can play a crucial role.

In the year under reporting DCVMN has worked shoulder to shoulder with all stakeholders helping augment capacity and bring down cost. We are confident that going forward DCVMN will continue to strive as a reliable partner!

Happy reading,

RAJINDER SURI *CEO-DCVMN*

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2022 HAS BEEN FULL OF PROGRESS & CHANGES

NEW LOGO AND BRAND IDENTITY!

We are proud to share DCVMN's rebranding! We have transformed and redefined our logo, brand colors, and taglines. Our goal is for our rebranding to reflect all the reforms and new projects that DCVMN is undertaking.



Developing Countries Vaccine Manufacturers Network

The drop in the middle of the logo represents the vaccine, which as a network we all aim to develop, manufacture and supply at a high quality and volume. The infinity symbol represents the path we trace together by being connected and interacting, by constantly evolving towards new horizons and collaborating with new partners and incorporating new members.

Each of our new colors holds a meaning. The navy blue incites trustworthiness and influence which we hold after being part of this field for more than 20 years. The color orange represents flamboyance and development, both for the countries that we are working with and for what we bring to the vaccine field. The light blue and green symbolize communication and the new perspectives that we are ready to bring. And finally the lilac shows our sophistication while reflecting our helpful and caring purpose.

New DCVMN Board Elected



At 22nd DCVMN Annual General Meeting, in Pune, India, the elections for Board members 2023-2025 was held, where all members put forward their votes for new committee members.

We are very pleased to welcome our new incoming Board members: Mr. Adriansjah Azhari, Mr. Tiago Tadeu Rocca de Moraes, Mr. Venkatraman Hariharan Sivaramakrishnan, Ms. Youngran (Rachel) Park, Dr. Mauricio Zuma Medeiros, Dr. Sunil Gairola, Dr. Andrew Zilong Wong.

We thank all the elected members for their interest and generous availability to voluntarily serve and guide the association!

DCVMs & COVID-19

During the COVID-19 Pandemic, vaccine manufacturers from developing countries demonstrated how they are uniquely positioned to rapidly innovate, manufacture and supply effective and safe COVID-19 vaccines. Together with the broader scientific community, public health, and regulatory bodies around the world, the industry will bring this experience and expertise to bear on new variants and on future pandemics.



1st

DCVM VACCINE

Was rolled-out in less than a year after the beginning of the pandemic.

~60%

Of the global contribution of COVID-19 vaccines are from DCVMs.

6

VACCINE IN EMERGENCY USE LISTING

WHO lists 6 COVID-19 vaccines from DCVMN members in Emergency Use Listing (EUL).

Who we are

The Developing Countries Vaccine Manufacturers Network (DCVMN) is a voluntary alliance of over 40 vaccine manufacturers from 15 developing countries, firmly engaged in innovation, research, development, manufacturing, and supply of highquality vaccines to 170 countries striving to enable equitable access to vaccines. DCVMN aims to protect people against known and emerging infectious diseases globally by increasing the production of high-quality vaccines in developing countries. It works to strengthen vaccine manufacturers through the provision of advocacy, professional training programs on technological and production improvements, and acting as a liaison to foster partnerships and funding. DCVMN also encourages technology transfer initiatives and educates the public about the availability of safe, effective and affordable vaccines for all people.

The Member Manufacturers of DCVMN



VISION

To protect people of all age groups in low-middle income countries and emerging economies against dreaded infectious diseases by augmenting the capacity of vaccine manufacturers in developing countries, to innovate, develop, produce and deliver a consistent and sustainable supply of quality vaccines at affordable prices to accelerate and reach the goal of global vaccine equity!

MISSION

To protect people of all age groups in low-middle income countries and emerging economies against dreaded infectious diseases by augmenting the capacity of vaccine manufacturers in developing countries, to innovate, develop, produce and deliver a consistent and sustainable supply of quality vaccines at affordable prices to accelerate and reach the goal of global vaccine equity!

STRATEGIC OBJECTIVES

To augment the capacity of vaccine manufactures and potentially other health technology producers, in developing countries, to innovate, develop, produce and deliver quality vaccines and other health technologies effectively at affordable prices for introduction in the national immunization programs in a sustainable manner;

To encourage and support sustainable public-private partnerships together with striving for global governance strategies oriented for economic incentives to vaccine manufacturers, ensuring sustainability in the market and to facilitate technical assistance to developing countries manufacturers in all aspects of production and distribution of vaccines;

To facilitate the exchange of ideas and experience among developing countries vaccine manufacturers and their counterparts in the developed world by promoting innovative models of ownership and sharing of intellectual property related to health improvement and by promoting the participation of developing country vaccine and other health technology manufacturers in international strategic planning and decision making;

To disseminate comprehensible information to the broader public health community and the general public to increase vaccine confidence;

To encourage compliance of members of the network with National Regulatory Authority (NRA) and WHO requirements.

DCVMN IN NUMBERS



170

Countries supplied with vaccines manufactured by DCVMN members, covering many MICs, LMICs and LICs



Publications in 2021-2022



Different vaccine products manufactured by DCVMN member companies, covering the most used and needed vaccines worldwide

Vaccine manufactured by most members





8

Different vaccine technology platforms are being used to develop COVID-19 vaccines between all of our 20 members that are engaging in the COVID-19 vaccine effort



Of the vaccines manufactured in the Network have WHO Prequalification

Our 2023 Objectives

To maximize vaccine reach by leveraging regulatory reliance mechanisms through WHO and NRAs

To augment professional development through meaningful training programs

To increase voice share of DCVMN in international stakeholders

To ensure rapid and successful Tech transfers leveraging new vaccine platforms



Our 2023 Strategies

- Continue to bring value addition to members through strategic collaborations with WHO, CEPI, Gavi, PATH, PAVM, WEF and WTO.
- Continue to provide high impact training programs with Virtual Reality modules, e-learning courses and Tech-Transfer trainings.
- 3 Initiate focus areas on: GMP, Quality Control, Quality Assurance, Regulatory Systems Harmonization, Supply Chain Excellence.
- 4

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Explore new initiatives to collaborate with leading Institutions and Universities, creating vaccinology training programs.

News from Members and DCVMN

INSTITUT PASTEUR DE DAKAR AND CEPI PARTNER TO ADVANCE COVID-19 VACCINE MANUFACTURING IN AFRICA

Dakar/Oslo, 18 Jan. 2022 - The Institut Pasteur de Dakar (IPD) and CEPI have signed a MoU to foster a partnership to advance a regional manufacturing hub for COVID-19 and other vaccines in Dakar, Senegal, with a new modular facility to manufacture up to 300 million doses of COVID-19 vaccine annually, for use in Africa. CEPI will provide strategic and technical support to IPD project to advance the development and delivery of vaccines manufacturing in Africa. CEPI will also advise on the implementation of an innovative vaccine filling and delivery solution, licensed from a third party and developed with CEPI's funding and support.

GLOBAL PANDEMIC PREPAREDNESS SUMMIT & CEPI REPLENISHMENT

Oslo, 8th Mar. 2022 – The Global Pandemic Preparedness Summit as a key milestone in rallying efforts to foster the development of new vaccines within 100 days of a future pandemic being identified and ensuring their equitable distribution around the world. We hope CEPI will meet its replenishment fundraising target to support its ambitious initiatives to reduce the risk of future pandemics and epidemics. The continued all round presence and support of CEPI right from identification of partners to development, scaling up and scaling out of vaccines has been critical success factor. We at DCVMN strongly believe that Mission 100 Days would turn out to be a pathbreaking step in the preparedness for any future pandemic.

BIONET ASIA PARTNERS WITH CEPI TO EXPAND COVID VARIANT PROOF-OF-CONCEPT PROGRAMME

Oslo/Bangkok, 25 Jan. 2022 - CEPI announced that it will partner with BioNet Asia to provide up to \$16.9 million to support clinical trials and analytical development of a novel vaccine that uses multiple mRNA molecules that encode for several SARS-CoV-2 target proteins from different variants. CEPI will support the researchers of a global and multidisciplinary consortium led by BioNet and composed of American and Thai universities and IVI, as they seek to establish preclinical and clinical proof of concept studies. If successful, this platform could also be used to enable rapid development of broadly protective vaccines against other Betacoronaviruses, as well as vaccines against Disease X—unknown pathogens with pandemic potential that have yet to emerge.

ACCELERATING RESEARCH AND DEVELOPMENT OF NEW VACCINES AGAINST TB: A GLOBAL ROADMAP

11th Mar. 2022 - DCVMN co-authored an article calling for the urgent development of a new, effective, and affordable TB vaccine for use in LMICs. A roadmap listing the actions needed to accelerate TB vaccine research and development using a participatory process was created. The vaccine pipeline needs more diverse immunological approaches, antigens, and platforms. Clinical development can be accelerated by validated preclinical models, agreed laboratory correlates of protection, efficient trial designs, and validated endpoints. There is a need for increased engagement of the industry for increased political commitment for new TB vaccines, and to address stigma and vaccine hesitancy.

SINOVAC POLIO VACCINE PREQUALIFIED BY WHO

Beinjing, 13th Jun. 2022 - Sinovac announced that it received the WHO prequalification for its Poliomyelitis Vaccine sIPV (Vero Cell, Inactivated Sabin strains). The vaccine will be available for UN agencies to purchase to support the global polio endgame strategy. Sinovac's sIPV is applicable for active immunization against polioviruses Type 1, 2, and 3 for children and infants aged two months and above. Sinovac will work closely with global public health institutions to promote the final step of polio eradication.

PANACEA BIOTEC RECEIVES UNICEF & PAHO AWARDS FOR SUPPLY OF PENTAVALENT VACCINE

New Delhi, 9th Oct. 2022 – Panacea Biotec has received long-term supply awards worth \$127.30 million from UNICEF and PAHO for supply of its WHO pre-qualified fully liquid Pentavalent vaccine, Easyfive-TT®. Paediatric vaccination plays an important role to achieve the SDGs set by the UN, in particular the target to reduce under-five mortality rate to less than 25 per 1000 live births. EasyFive-TT is a ready-to-use combination vaccine that does not require preparation by healthcare workers at the clinic, reduces the number of visits to vaccination centers, and reduces the overall cost of immunization for all stakeholders.

CANSINO: WORLD'S FIRST COVID VACCINE YOU INHALE IS APPROVED IN CHINA

Tianjin, 7th Oct. 2022 - China became the first country to approve a needle-free, inhaled version of a Covid-19 vaccine made by CanSino Biologics Inc. China's National Medical Products Administration approved CanSino's Ad5-nCoV for emergency use as a booster vaccine. The vaccine is a new version of CanSino's one-shot Covid drug, the inhaled version can stimulate cellular immunity and induce mucosal immunity to boost protection without intramuscular injection. Companies are looking into developing inhaled versions of vaccines to stimulate antibodies in nasal and airway tissues to defend against coronavirus. They are needle-free and can be selfadministered, broadening their appeal to vaccine-hesitant people and potentially easing pressure on health-care resources.

WHO: GLOBAL ROLL-OUT OF 12 BILLION COVID-19 VACCINE DOSES LARGEST-EVER BUT ACCESS AN ISSUE

India, 21st Oct. 2022 - Addressing the DCVMN AGM virtually, WHO director-general, Dr Tedros Adhanom Ghebreyesus, flagged the issue of inequities in access to COVID-19 vaccines even after the rapid roll-out efforts by saying, "These inequities are due partly to the fact that globally vaccine production is too concentrated. To address this, the WHO and our partners have established the mRNA Tech Transfer hub in South Africa to facilitate the know-how in low & middle-income countries". Adar Poonawalla, CEO of SII, cohost the 23rd DCVMN AGM in Pune, added by saying - "Today, the world is more aware and focused on chalking out an ambition-to-action roadmap for future pandemic preparedness. For that, building the infrastructure and regulations to ensure global equity and timely access to vaccines is the foremost priority".

DEVELOPING COUNTRIES SUPPLIED 60% OF COVID VACCINES

Pune, 21st Oct. 2022 - At the 23rd DCVMN AGM in Pune, speakers discussed glaring inequities in Covid vaccine development and production. Rajinder Suri, CEO of DCVMN, said the Covid pandemic helped put global vaccination in focus - "However, we also got to know the disparity in vaccine production and funding between developing and developed countries. As per our data, out of the 12.8 billion doses manufactured in the past 20 months, 60% was manufactured by developing countries mainly by India, China, Brazil, Indonesia and South Korea. But compared to the \$51 billion in investment the developed countries received, the developing nations got only \$5.6 billion". Suri added that despite such low investment and funding, the developing countries went on to make huge contributions towards both development and manufacturing of the Covid vaccines.

BIOTECHS, DCVMS AND PHARMA UNITE BEHIND A PROPOSAL TO G20 AND G7 OFFERING A PRACTICAL SOLUTION FOR BETTER ACCESS TO VACCINES FOR FUTURE PANDEMICS

25th Oct. 2022 - The BIO, DCVMN and IFPMA have been key players in the historic effort to scale up the manufacturing of COVID-19 vaccines. Today, the three trade bodies representing vaccines innovators and manufacturers are contributing to the G7 and G20 discussions an offer of a practical solution to vaccine equity for future pandemics. Specifically, the proposal offers to reserve a real-time allocation of vaccines production for vulnerable populations in lower-income countries. They invite stakeholders to accept and include this solution in their future pandemic preparedness response plans, whilst impressing upon governments that for the proposal to succeed the health systems in LICs need to be better prepared to absorb and deliver vaccines and treatments, while HICs need to provide the necessary political and financial support.

NEED TO ENSURE A GLOBAL PANDEMIC TREATY, SAYS DCVMN CEO

Pune, 22nd Oct. 2022 - The DCVMN CEO said that there have been regional imbalances, and referring to Africa pointed out that the country is manufacturing only one percent of their total requirement of vaccines. "Hence the rest is being imported. Now, Africa's Centre for Disease Control has floated a platform so that there is a plan in place and by 2063 they would have more than 60& of local production," Rajinder Suri, CEO of DCVMN, said. At a panel discussion on Sustainability and Lessons Learnt speakers said that DCVMN can interact with governments and vaccine manufacturers to identify training initiatives for future pandemic preparedness. Panelists also urged to refrain from politicizing the response to the pandemic.

DCVMS SUPPORT IFPMA PROPOSAL ON PANDEMIC READINESS

25th Oct. 2022 - The BIO and DCVMN have agreed to jointly endorse the 'Berlin Declaration Framework', proposed by IFPMA, in July. The proposal outlines strategies, including reserving an allocation of real-time production of vaccines for distribution to priority populations in LICs for future global pandemics. The endorsement of the proposal was made following the recently-concluded annual meeting of DCVMN in Pune. Rajinder Suri, DCVMN CEO, said that the strategy involved multiple approaches, including allocating a percentage of production for priority populations, diversifying manufacturing (and looking at end-to-end supplies involving raw-material, packaging), training people to handle biological products, and nudging governments to prepare the ecosystem to absorb new technologies for production or distribution.

SUSTAINABLE VACCINE MANUFACTURING IN LOW- AND MIDDLE-INCOME COUNTRIES

2nd Nov. 2022 - DCVMN co-authored an article discussing the importance of sustainable manufacturing of vaccines in developing countries to increasing equitable access to vaccines and pandemic preparedness globally. Sustainable manufacturing requires that organizations engaged in the development, production and supply of vaccines have viable business models and incentives to manufacture vaccine products. This study assesses the technical capabilities, manufacturing capacities, and aspirational plans of DCVMs, exemplifying the business models and strategies undertaken to sustainably manufacture vaccines in developing countries. The public health importance of a healthy vaccine industry which enables manufacturers is discussed throughout.

HILLEMAN LABORATORIES WHITE PAPER – "VACCINES, TODAY AND TOMORROW"

Singapore, 14th Dec. 2022 - The new Hilleman Laboratories white paper entitled "Vaccines, Today and Tomorrow" discusses the current global vaccine ecosystem and what we can do to accelerate broad access to vaccines for populations in LMICs. Having reviewed the literature, studied the data and interviewed many thought leaders from the global vaccine ecosystem, including DCVMN CEO, this white paper attempts to assess the current situation and chart a course towards an equitable future by highlighting the fact that vaccine availability is just one of the many factors for low vaccination rates in LMICs. As such, more needs to be done to strike a balance between national interests, global public health objectives, and commercial incentives. Building partnerships with relevant health ecosystem stakeholders is essential to develop innovative and affordable vaccines and biologics.

BIOVAC SIGNS DEAL TO DEVELOP AND MANUFACTURE ORAL CHOLERA VACCINE

Cape Town, 24th Nov. 2022 - Biovac concluded a ground-breaking licensing and technology transfer agreement with IVI to develop and manufacture oral cholera vaccine for African and global markets. The project will aid Biovac in establishing drug substance manufacturing expertise for producing the antigen/raw material that is needed to manufacture the vaccines. This is one of the remaining steps in the vaccine manufacturing value chain that is currently missing, not only at Biovac, but across the African vaccine manufacturing landscape. This collaboration with IVI will enable Biovac to licence and transfer technology to boost production volumes and establish and validate the capacity for scaling up GMP, local production of clinical trial products, and end-to-end vaccine manufacturing in Africa for regional and worldwide use.

IABS/DCVMN WEBINAR ON NEXT GENERATION SEQUENCING

21st Dec. 2022 - This report written IABS and DCVMN as an introduction to the technical and bioinformatics concepts of Next Generation Sequencing (NGS) and to some of the strengths and limitations of using the technology for those working in vaccine production or development. The application of NGS to supplement or replace current in vivo and in vitro assays in adventitious virus testing during vaccine production is promising; however, assay performance needs to be demonstrated, which may include laboratory and bioinformatics work. Efforts from regulatory authorities, industry, and researchers are ongoing to facilitate validation and establishment of NGS as a new method for virus detection.

DCVMN Training Programmes

WORKSHOPS

DCVMN has increasingly coordinated interactive training workshops [1] on trending and relevant topics for honing the skills of professionals from its member companies since 2013.

Throughout the year of 2022, the Network organized a range of meetings and workshops, mainly covering its five expert areas: Pharmacovigilance (PV) & Medical Coding, Clinical Development & Benefit-risk Management, Supply Chain & Packing Technologies, Regulatory Affairs & Collaborative Registration Procedure (CRP), and 3R's which were mostly held in virtual format [2].

Around 600 attendees actively engaged in the various workshops and Expert Working Group meetings, held regularly throughout the year, to nurture knowledge-rich skills with open discussions on best-practices. In total, there were 22 workshops led and facilitated by DCVMN Secretariat in 2022, as detailed in the chart below. In addition to private DCVMN meetings, corporate members also participated in a varied range of other activities, workshops, and in-depth trainings organized by WHO, UN, CEPI, GAVI, CHAI, and other international stakeholders.

Areas of Work/Topic	Number of Workshops & WG meetings	Notes
Pharmacovigilance (PV) Working Group[3] & Medical Coding Best Practices[4]	5	1x PV workshop plus 4x WG meetings
Clinical Development Working Group[5] & Benefit-risk management[6]	4	1x Benefit-risk Management workshop plus 3x WG meetings
Supply Chain Working Group[7] & Packing Technologies[8]	4	1x Packing Technologies workshop plus 3x WG meetings
Regulatory Working Group[9] & CRP[10]	5	1x CRP workshop plus 2 WG meetings
3R's Working Group[11]	4	4x WG meetings
Total	22	

- [1] Training materials are openly available at https://dcvmn.org/dcvmn-training-workshops/
- [2] List of Expert Working Groups at https://dcvmn.org/expert-working-groups/

[5] Clinical Development Working Group at https://dcvmn.org/clinical-development-medical-affairs-working-group/

[7] Supply Chain Working Group at https://dcvmn.org/supply-chain-working-group/

[9] Regulatory Working Group at https://dcvmn.org/regulatory-working-group-2/

[11] 3R's Working Group at https://dcvmn.org/dcvmn-3rs-working-group/

^[3] Pharmacovigilance Working Group materials at https://dcvmn.org/pharmacovigilance-working-group-2/

^[4] PV Workshop at https://dcvmn.org/PV-Workshop-Introduction-on-Medical-Coding-practices-Session-1/; https://dcvmn.org/PV-Workshop-Introduction-on-Medical-Coding/; PV Workshop: Data Retrieval and Presentation – Best Practices – DCVMN

^[6] Workshop on Clinical Benefit-Risk Methodology and Templates at https://dcvmn.org/Workshop-on-Clinical-Benefit-Risk-Methodology-and-Templates/

^[8] Workshop on New Packing Technologies at https://dcvmn.org/Workshop-on-new-packaging-technologies/

^[10] Workshop on Benefit Risk Methodology and Templates at https://dcvmn.org/Workshop-on-Clinical-Benefit-Risk-Methodology-and-Templates/

E-LEARNING

Since December 2016, DCVMN offers self-paced, flexible e-learning courses to professionals interested in strengthening their technical and scientific knowledge to produce safe, effective, and high-quality vaccines for all people. E-courses are openly accessible at https://moodle.dcvmn.net/, upon registration.

Participants can freely choose any of the 26 e-courses offered on the DCVMN elearning platform. At the end of each e-course, learners can voluntarily attempt a Q&A quiz, and those scoring 80% or more can download a customized personal ecertificate of achievement. Over 2022, around 6500 enrolments were recorded in the e-learning courses, of which 2742 achieved certificates (figure below). Dropouts indicate enrolled participants who did not complete the e-courses, for personal reasons. In 2022, one new e-course on "Clinical Benefit Risk Assessment" was added, and almost 1700 participants enrolled to the DCVMN available e-courses and over 600 earned e-certificates, throughout the year, demonstrating increasing interest in e-learning platform, since its inception.

Cumulative number of e-training enrollments and cumulative number e-certificates achieved from 2017 to the end of 2022. Platform available at https://moodle.dcvmn.net



WEBINARS

DCVMN webinars constitute a cross-sectorial regular platform for its community's upskilling and networking. Since 2015, high-performance experts from DCVMN resource members, partner organizations, and sponsors have voluntarily conducted webinars on novel technologies and trending developments according to the demand from vaccine industries, approximately on a monthly basis.

To notice, the Network held 13 webinars in 2022, leveraging the discussions about innovative solutions in vaccine quality management, sustainability, automation, R&D within global industry [12]. The attendance has been analyzed in terms of number of connections (individuals or group of people), companies, and countries by session. The bar chart shows a higher number of webinars, steady number of countries, and oscillating number of attendees after Q1. In comparison to 2021, there has been a ~25% increase in the averages of all three metrics in 2022.

Number of connections, companies and countries at DCVMN webinars in 2022. Note that one connection may correspond to a group of persons attending. Chart graciously Prepared by Ms. T. Lacerda.



HILLEMAN-DCVMN TECHNOLOGY TRANSFER TRAINING

Having recognized the importance of technology transfers, DCVMN in collaboration with Hilleman Laboratories, Singapore, launched the Hilleman-DCVMN Technology Transfer Training Programme for vaccine manufacturers to learn, share and impart knowledge on vaccine production, and specifically in the tech transfer process and requirements.

The training workshop consists of two immersive weeks of learning, with daily lectures alongside hands-on laboratory sessions. It offers essential professional exposure and guidance on technical mastery which are crucial during process optimization, development, and transfer. Participants learn about the importance and the actual implementation of technology transfer for vaccine development and manufacturing, to strengthen vaccine capabilities across the various regions. The training fee, flights and accommodation of the attendees are fully covered.

The first DCVMN-Hilleman Tech Transfer Training took place from June 20th to 30th, 2022. It was composed of 15 participants from 7 DCVMN companies. To assess the learning of the participants and the effectiveness of the programme a 3-step evaluation was done. A pre-training test was conducted to evaluate the understanding level of the participants (day 0), this was followed by a performance evaluation upon completion of the training program (day 10). Lastly, a day-90 monitoring of outcomes on job performance was collected and analysed in October 2022.

I have benefitted tremendously from the HL-DCVMN Tech-Transfer Training Programme. The trainers covered major topics in production and technology transfer, and I now have a solid foundation to build on. I particularly appreciated the general overview of the role of biologics in the post-pandemic world and the forecast for this financial sector

I have gained deep insights of what an effective tech-transfer entails through the HL-DCVMN Tech-Transfer Training Programme. I found the hands-on training, labbased equipment demonstration, interactive group discussion sessions, sharing sessions, and problem-based case studies useful.

VIRTUAL REALITY

In 2022, DCVMN has continued to further develop its Virtual Reality (VR) training modules, related to laboratory and facility hands-on experiences. DCVMN is the first global organization utilizing novel VR technology to provide training in the vaccine manufacturing field!

VR is the most powerful tool to replace and simulate physical onsite training for employees, especially in core areas where even a small error can cause contamination requiring facility closure followed by intensive cleaning validation and revalidation taking months of loss of production. It gives researchers and manufacturers the opportunity to conduct experiments in life-like virtual scenarios, in a safe, controlled, measurable and repeatable way.



A novel VR training module was developed in collaboration with experienced VR service provider - Global Vision Communication (GVC) - based in Switzerland, and hand-in-hand with QA experts from one of our members. This VR training focuses on clean room and aseptic practices in the fill-finish procedure. It looks at the steps and interventions taken to ensure room sterility and eliminating the risk of possible contamination of the core facility. The training module is available for download on the DCVMN website since the beginning of January 2023 [13].

A second VR experience is being developed which focuses on the cleanroom gowning procedure. This new VR training will be available in the spring of 2023.

The goal for 2023 is to showcase the VR trainings and hold regional workshops to familiarize trainers from member companies on how to use the VR, so that they can successfully implement the training in their facilities. We will also create questionaries for the trainers so that they can report on the effectiveness of the VR as a training tool in their company.

Expert Working Groups

The expert Working Groups (WGs) are formed by DCVMN member manufacturers around areas of common interest, including Supply Chain & Traceability, Regulatory Affairs, 3Rs & PSPT, Pharmacovigilance & Risk Management Plan, Clinical Development & Medical Affairs, and are supported by independent senior expert consultants. The WGs hold regular meetings, sharing best-practices and projects of common interest to most members. The WG activities are currently funded with donors' funds, to develop and analyze surveys, design projects, draft white papers, training & communication materials. Since 2019, the Donors Advisory Committee and WG members act on a voluntary non-remunerated basis, similar to Board members, which empowers the members to get directly involved in leading the working groups and related Network activities.



Supply Chain & Traceability

The goal of the supply chain expert group is to share best practices and find common solutions for companies to increase the efficiency and effectiveness of their vaccine supply chain through innovation in the manufacturing and distribution stages. Presently, the group focuses on tracking vaccines (traceability), stockpiling and considering new packaging technologies. It develops position papers that can inform DCVMN members and the wider global immunity community on the specific actions DCVMN members could undertake to improve the vaccine supply chain, including any resource implications.



Regulatory Affairs

The regulatory affairs working group shares the best practices in regulatory science and regulatory approaches. The group seeks to collaborate for the identification of regulatory challenges at both the pre-marketing and post-marketing stages in the vaccine life cycle. It explores potential opportunities for increased efficiency of regulatory processes worldwide, improvement of the vaccine registration procedures and processes (pre-registration stage) in countries, and to identify challenges and opportunities for the improvement of post-approval changes (PACs) management at all stages. The proposals from the group are shared widely with partners and vaccine stakeholders who can encourage regulators in implementing some of the proposed changes for improvement.

3Rs (Replace, Reduce, Refine)



DCVMN 3Rs Working Group aims to promote the implementation of the 3Rs Principle - replacement, reduction and refinement - of animal testing in the vaccines' batch release process and the removal of obsolete tests (4th R) through the establishment and standardization of new test assays for vaccines and of manufacturing methods complying with the 3Rs principles. The implementation of 3Rs would bring significative impact in terms of cost saving (from few dollars per test up to thousands) and reduction of products' release time to the population, down to few days instead of weeks.

DCVMN 3Rs WG approach is based on:

- Sharing members' successful case studies from both the technical and business perspective (workshops and working group calls).
- Providing access to external expertise (webinars, workshops trainings).
- Creating dedicated projects.
- Actively participating in the international projects and global dialogue.



Pharmacovigilance & RMP

The vaccine pharmacovigilance (PV) working group identifies the needs to improve and strengthen pharmacovigilance systems for vaccine manufacturers in emerging countries so that DCVMN member companies are equipped with up-to date knowledge on how to improve global vaccine safety monitoring, operational pharmacovigilance capabilities and proactively identify and respond to potential safety issues, including resource implications, which are aligned with WHO and relevant national regulatory requirements.

Current WG Projects

Clinical Development & Medical Affairs Working Group

Designing and executing a successful clinical development plan for any candidate vaccine requires a solid scientific, medical, operational and regulatory knowledge and expertise, to comply with regulations and assure adequate benefit-risk balance for the product to be used in mass vaccination of healthy populations. To support interested manufacturers in reflecting accelerating vaccine development, a Clinical **Development & Medical Affairs Working Group** (CDMA WG) was established in January 2022 and launched in March 2022, as to needs of members. Apart from the need of highlighting the importance of benefit-risk analysis in all the CDMA activities, developing a List of key Standard Operating Procedures (SOPs) for clinical operations was identified as one of the prime objective by the WG. Three additional Clinical WG meetings were convened, one inperson in Geneva (June 2022) and two others online, in December 2022 and February 2023, and the CDMA WG agreed on a list outlining 46 key SOPs for supporting clinical operations. [14].



Clinical Development & Medical Affairs Working Group

The Clinical and Medical Affairs Working Group (CDMA WG) identifies and assesses the members' capacity to develop and implement a benefit-risk approach for their Clinical and Medical activities. The purpose of the working group is to ensure that DCVMN member companies are equipped with state-of-the art methodology to provide vaccines according to international standards and guidelines, aligned with national and international regulatory requirements. In addition, a publication on a survey aimed at informing stakeholders on considerations to strengthening clinical development activities and preparedness for vaccine manufacturers from emerging countries was published [15].

	Vaccine: X 13 (2023) 100255	
	Contents lists available at ScienceDirect	
	Vaccine: X	
ELSEVIER	journal homepage: www.elsevier.com/locate/jvacx	

Strengthening clinical development activities and preparedness for vaccine manufacturers from emerging countries: Results of a survey

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The purpose of this study was to assess the approaches and practices related to Clinical Development functions, to identify industry needs in terms of organizational development and training needs encompassing four working areas: (1) the organizational structure and the activities conducted by the clinical functions; (2) the clinical trial design ability and the management of clinical trial documents; (3) the clinical trial management and monitoring activities; (4) the quality aspects of clinical activities. The results suggest that the great majority of respondents is engaged in intense clinical development activities to achieving a high level of preparedness in emerging countries, for development of new vaccines against future regional epidemics and global pandemics.

Pharmacovigilance Working Group

In April the cross-cutting initiative "The Risk Management Project" between Regulatory Affairs and Pharmacovigilance (PV) was finalized. The objective of the project was to strengthen the capacity of DCVMs to develop risk management plans (RMPs) required for vaccine registration and WHO PQ submissions to meet the ICH Guidelines. The project started in March 2021 and was based on a "learning-by -doing" concept and organized in 5 phases. At the end of December, nine RMPs were submitted to the DCVMN secretariate. The submitted RMPs were reviewed by 3 RMP experts and individual 1:1 feedback was provided in January 2022. The final workshop was then held with members in April 2022 to discuss critical areas of the RMP. A practical memorandum on important and critical areas of the RMP was published and presented at the workshop and then circulated to all members [16]. This tool is to be used when selfassessing a company RMP to find out if critical areas have been adequately addressed.

The main project identified for 2022 was the Active Vaccine Safety Surveillance (AVSS). Over the course of 2022 this project was spearheaded by the DCVMN PVWG whose intention was to develop adequate training via a series of online webinars to its members from which members would gain the importance of establishing safety governance, a basic introduction to AVSS, and guidance on implementation of AVSS within respective organization [17]. Following the training, interested members will be invited to prepare and implement an AVSS program which will be worked upon and reviewed in consultation with DCVMN expert consultants. The experiences of these members after implementation will be shared with the PVWG and based on findings a WHO published paper will be written in

collaboration and an e-learning module will be created for the DCVMN Moodle platform.

In 2022, three online workshops where held on the PV post-licensure training done by PATH including MedDRA training to improve coding of medical terms within PV [18]. This allows much more accurate assessment of AEFIs for signal detection and periodic reporting. Companies also need training to understand that coding conventions within each company are required to ensure cohesion. The ability to create Standard Medical Queries is another component of MedDRA Training which is important in Pharmacovigilance. If for example, an NRA requests a company to give an assessment on a particular AEFI, the company can pull data from its own safety database into MedDRA and have a complete picture on all the relevant cases related to the particular AEFI for safety analysis.

A joint Face-to-Face Workshop held in June with the Clinical/Medical WG, to discuss the role of PV activities in clinical aspects of vaccines in pre-and post-licensure. From this meeting, the PVWG published on the DCVMN website a PVspecific SOP Master List with Explanatory Notes for the PV activities in the pre-and postlicensure period [19].

Lastly, to improve PV systems for the future, work on Pharmacovigilance Electronic Safety Data Management was done. A white paper is being compiled on providing a holistic view on the requirements for adoption and implementation of an electronic safety data management system and an acquisition tool and RfP template have been drafted to provide support for members who are not experienced in this field.

[17] https://dcvmn.org/avss-pharmacovigilance-workshop/

[19] https://www.dcvmn.org/Project-Participants-List

^[16] https://www.dcvmn.org/DCVMN-manufacturers-trigger-successful-Collaborative-Registration-Procedure-CRP

^[18] https://dcvmn.org/PV-Workshop-Introduction-on-Medical-Coding-practices-Session-1/; https://dcvmn.org/PV-Workshop-Introduction-on-Medical-Coding/

Regulatory Working Group

The Regulatory Affairs WG (RAWG) [20] seeks to identify and address regulatory challenges for the vaccine life cycle, and potential opportunities for increased efficiency of regulatory processes worldwide.

Promote the use of the WHO Collaborative Registration Procedure (CRP) to allow for greater global access to products and reduce regulatory registration hurdles, a member-wide survey was distributed to determine member engagement and current understanding of WHO CRP. Based on the information collected a workshop was organised by DCVMN in collaboration with WHO in Geneva in September 2022 for DCVMN RAWG members and WHO to discuss and develop a successful roadmap for CRP to improve the use of the procedure by DCVMN manufacturers. The 2023 roadmap includes: Participation in six WHO CRP regional advocacy workshops; WHO to hold workshops with NRAs and members on 5-year plan to change SRA to WLA; and public health impact vaccines will be identified, and a CRP pilot program will be applied by mid-2023. A Post Approval Change (PAC) Management training workshop was held in November 2022, addressing changes to PACs and the new module on regional PACs requirements. With 99 participants from DCVMN and IFPMA, a common letter was drafted and sent to amend WHO TRS 993, Annex 4, to improve the way CMC PACs are managed globally to assure timely supply of vaccines. In the lead-up, discussions with the International Coalition of Medicines Regulatory Authorities (ICMRA) were held that covered:

- Industry Associations' proposal
- Reliance for PACs and hybrid GMP inspections
- Labelling flexibility
- Manufacturing and distribution related matters



Supply Chain Working Group

The Traceability Consortium under Supply Chain Working Group [21] was established in 2021, to coordinate the non-competitive knowledge exchange among six manufacturers interested in the implementation of GS1 traceability tools. Four of the interested manufacturers have received technical training and planning of their projects, partially sponsored by a donor, for local expert support, namely in India and China (Biological E, Bharat, Innovax, CNBG). Other two manufacturers engaged on traceability implementation on a self-financing basis (Biofarma, Sinergium). DCVMN secretariat encouraged, supported and coordinated the technical support, with the collaboration of an expert consultant.

In 2022, the traceability project helped interested DCVMN member manufacturers to complete the global traceability standards implementation for 6 vaccines to be supplied both at national and international level, at primary or secondary packaging levels. Furthermore, a warehouse management system (WMS) implementation upgrade was also supported to enable traceability of supplies and raw materials, used to manufacture and supply vaccines, so to generate an end-to-end traceability, from raw materials to final product and final users. Only one manufacturer could commit to carry out the planning and training within the agreed time period, completed on 31st October 2022. A publication summarizing the process and outcomes of the traceability pilot studies has been submitted for publication.

In addition, a report of an open discussion among manufacturers on the benefits and challenges of innovative packaging technologies has been published to engage a broader audience [22].

COMMENTARY

ADVANCED RANUFACTURING WILEY

Innovative vaccine packaging technologies: Perspectives on benefits and challenges of compact prefilled auto-disable devices and polymer containers

Sonia Pagliusi¹[©] | Stephen W. Jarrett² | Rachel Park³ | Yudha Bramanti⁴ | Ravi Menon⁵ | Courtney Jarrahian⁶ | Collrane Frivold⁶ | Lingjiang Yang⁷

Illustrations of 2D codes on primary and secondary vaccine packages implemented by the consortium members between June 2021 and June 2022.

Primary Packaging

Secondary Packaging



3Rs Working Group

In 2022, the 3Rs WG has focused on three main projects [23]: The Pertussis Serological Potency Test (PSPT) Consortium, the Diphtheria and Tetanus Single Dilution Assay Project and the Familiarization with Monocyte Activation Test (MAT).

The PSPT Consortium was established by DCVMN in 2020 and funded by NIIMBL and it reached some important milestones in 2022. The PSPT Standard Operating Procedures have been improved and guided by all the 10 participating laboratories in the performance of their in-house testing. The critical antigen reagent specific for the PSPT has been produced by a Contract Manufacturing Organization and distributed to all participating laboratories. In April 2022, a hybrid meeting to discuss the project outcomes with international stakeholders which took place New Delhi, India. PSPT results from all the 10 participating laboratories demonstrated that the PSPT is fit for purpose and 8/10 laboratories are willing to carry out full validation studies. The coating antigen materials of Bordetella pertussis, produced in collaboration with BioLyo (Belgium), have been independently characterized by Intravacc and reviewed by the Steering Group, and 1000 vials (out of 2000) have already been donated to all participating laboratories under Material Transfer Agreements. Currently, two papers are being prepared for publication.

Following the workshops dedicated to the "Single Dilution Assay" [24], DCVMN members expressed interest to participate to join a demonstration project. The single dilution assay for the potency calculation of Diphtheria-Tetanus containing vaccines reduces the number of animals required for both the in vivo challenge and the serological potency assay.

The objective of the Diphtheria and Tetanus Single Dilution Assay Project is to support interested members participating in the project to create implementation plans of the single dilution assay. The project aims to create a communication channel between members and external experts on the topic, allowing all the parties to safely communicate respecting each other's' confidentiality. Currently, 6 participating companies have shown interest on this project and will receive dedicated support from external experts which will provide theoretical knowledge and common form to support the creation of their own implementation plans. External experts from ISS (Italy) and Sciensano (Belgium) will support on this project.

The 3Rs Working Group provided the members with a webinar, an e-learning course and a Virtual Reality [25] experience to help members to familiarize with the MAT, which is an alternative test to the Rabbit Pyrogenicity Test. The MAT is designed to test parenteral drugs, biologics and medical devices for all classifications of pyrogens. A hand on training was given to members for MAT test in April 2022 at New Delhi workshop.

In October 2022, the DCVMN 3Rs WG also participated at the World Vaccine Congress in Barcelona, Spain, where stakeholders from EDQM, US FDA, IFPMA, WHO and the Bill & Melinda Gates foundation agreed on the need to harmonize regulations to facilitate implementation of non-animal testing to avoid delays in supply vaccine shortage and access, remove and replace animal testing and to further secure the acceptance of these approaches and push for a truly global regulatory alignment.

^[23] https://dcvmn.org/dcvmn-3rs-working-group/

^[24] https://dcvmn.org/DCVMN-3Rs-Workshop-Implementing-the-Diphtheria-Tetanus-Single-Dilution-Assay/

^[25] https://dcvmn.org/vaccine-testing-using-monocyte-activation-test/

COVID-19 Committee

The DCVMN COVID-19 Committee was established at the height of the COVID-19 pandemic with the following objectives :

- Prime COVID-19 vaccine candidates;
- Disseminate technical information relating to COVID-19 vaccine development;
- Solutions provided by organizations such as CEPI, etc;
- Assess and share technologies important for COVID vaccine development;
- Develop and support solid bases for statements to support DCVMN dialogue with global stakeholders and in public meetings.

The committee held its first meeting on June 19th, 2020, and regular triweekly meeting was held afterwards. Since June 10th, 2021, the meeting series were conducted monthly every second Thursday.

The agenda the meeting include of epidemiological updates, updates on on total vaccine doses administered, Partnership updates, Updates on CEPI initiatives, Reports from sub committees. Other agendas include joint meetings with Regulatory Systems Working Group, presentations from DCVMN group discussion with invited members. speaker, and webinars.

DCVMN members have participated in CEPI's initiatives which include numerous work stream SWAT teams and CMC platform protocol templates working groups. The SWAT teams consisted of four work streams namely, enabling sciences, clinical development and operations, manufacturing, and regulatory advisory group (RAG) whereas CMC platform template working groups have the objective in designing CMC platform protocol templates as quidance for regulators and manufacturers in expediating the development of pandemic vaccines in conjunction with CEPI's 100 days mission. The protocol templates consist of two areas: comparability and manufacturing process validation.



DCVMN Representation at Global Meetings

ADVOCACY AT HIGH LEVEL FORUMS

WHO	ACT-Accelerator Tracking and Monitoring Task Force
STHE SLOBAL	Country Coordinating Mechanism (CCM)
CEPI	CEPI Joint Coordination Group (JCG)
	Gavi Vaccine Investment Strategy (VIS)
	Partnerships for African Vaccine Manufacturing (PAVM)
G2O INDONESIA 2022	G-20 Health Group
WØRLD ECONOMIC FORUM	Regional Vaccine Manufacturing Collaborative (RVMC)
NAL WORLD ROTEOTE	COVAX Manufacturing & Supply Chain Task Force Leadership Team
WØRLD ECONOMIC FORUM	World Economic Forum
WHO	World Health Organization
TANDE OR GRANINTION	World Trade Organization

DCVMN Representation at Global Meetings



23rd Annual General Meeting



DCVMN 23rd Annual General Meeting

23rd Annual General Meeting

GLOBAL EQUITY AND TIMELY ACCESS: COVID-19 & BEYOND

DCVMN held its 23rd Annual General Meeting (AGM) from 20th to 22nd October 2022; the first being held in a hybrid format after two years of meeting virtually due to the pandemic. The meeting was co-hosted in Pune by Serum Institute of India and inaugurated by Dr Mansukh Mandaviya, Honorable Union Minister of Health and Family Welfare and Minister for Chemicals & Fertilizers Government of India.

The AGM gathered over 365 delegates and more than 90 highlevel speakers for three days of presentations, discussions, and networking. This event is a crucial platform for vaccine manufacturers from developing countries to voice their experiences, challenges and successes with global stakeholders.

Throughout the 13 highly productive sessions, there was a clear red thread - vaccine equity and timely access. As demonstrated during the COVID-19 pandemic DCVMs have diverse capabilities to develop, produce, and supply vaccines for local and global use. The key lessons drawn from this were discussed to highlight how they can used to equip DCVMs for better pandemic preparedness and create a sustainable vaccine ecosystem.

A subject that was repeatedly underlined was the crucial role of South-to-South collaborations and funding support to achieve sustainable vaccine manufacturing in LMICs. This went hand in hand with the requirement to increase regional vaccine capacity, especially in Africa.

The importance of reliance mechanisms & innovations in regulatory mechanisms, like revised guidance on EUL documents, in bringing added value to the manufacturers was also widely discussed. To establish reliable coordination and acceptance between international regulators new innovations, technology transfers and trainings are key to provide quality and efficacy guarantees and have sustainable vaccine equity.

Lastly, to ensure that all the work is not wasted, countries must tackle vaccine hesitancy and invest in innovative methods to help facilitate and increased administration.

Financial Statements

BALANCE SHEET AS AT 31 DECEMBER 2022

ASSETS	31.12.2022	31.12.2021
AGGETS	USD	USD
Current assets		
Liquidities	2'868'688.09	3'381'648.69
Membership fee to receive	45'000.00	0.00
Provision for loss on membership to receive	-15'000	0.00
Advance deposit for expenses	10'000.00	5'000.00
Regus deposit	62.69	63.66
Prepaid expenses and accrued income	22'743.65	7'497.59
Total current assets	2'931'494.43	3'394'209.94
TOTAL ASSETS	2'931'494.43	3'394'209.94
LIABILITIES		
Short-term liabilities Notes		
Payables	39'719.09	13'100.49
Donations carryover 3.1	82'251.16	496'909.02
Accrued expenses	31'042.98	49'566.18
Total short-term liabilities	153'013.23	559'575.69
Unrestricted reserves		
Capital	2'834'634.25	2'815'806.88
Translation adjustment	0.00	5'546.31
Net result for the year	-56'153.05	13'281.06
Total unrestricted reserves	2'778'481.20	2'834'634.25
TOTAL LIABILITIES AND RESERVES	2'931'494.43	3'394'209.94

INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2022

	2022	2021
Income	USD	USD
Members contributions	Notes 573'000 (548,000.00
Provision for loss on members contributions for previsous year	-15'000.0	
Reversal provision for loss on members contributions for previsous year	0.0	0.00
Loss on members contributions	0.0	0.00
Donations received	710'0000.0	00 284'487.97
Carryover from previous year	496'909.0	1'028'694.25
Donations carryover to the next year	3.1 -82'251.1	-496'909.02
Reimbursement of donations	0.0	-66'876.66
Annual meeting contribution participants	12'742.3	35 1'150.00
Total income before financial income	1'695'400.2	21 1'299'546.54
Total income	1'695'400.2	21 1'299'546.54
Operating expenses		
Best practice supply WG	-221'213.6	-79'375.38
Training Initiative	-243'003.3	-128'000.49
Regulatory Forum initiative	-207'682.3	-184'733.41
Knowledge exchange and databases initiative	-13'109.2	-46'803.54
Pharmacovigilance initiative	-83'858.9	-30'867.05
Travel	-15'573.7	0.00
Annual General Meeting	0.0	-20'911.25
Total operating expenses	-784'440.7	'3 -490'691.12
Staff Costs		
Salaries	-630'464.9	91 -527'146.62
Social contributions AVS/AI/APG/AC/PCFam	-29'843.9	-29'529.93
Social and accident insurances	-5'979.2	-6'298.67
LPP contribution	-20'905.5	-20'213.85
Total staff costs	-687'193.6	-583'189.07
Other operating expenses		
Office rental	-7'659.4	-8'028.10
Office supplies	-20'924.8	-14'756.06
Accounting services	-26'414.2	24 27'808.00
Legal consulting	-36'767.3	
HR and payroll services	-19.931.8	32 -2'838.55
Technical support by FVMR Hub	0.0	-41'304.36
Membership fee and donation	-26'000.0	
Financial audit	-10'847.6	-11656.95
Publications	22/575	19 2/001 52
Travel expenses	-23 373.	17 0.00
Miscellaneous	-116 1	4 -1'102 19
Total other operating expenses	-238'035 8	-191/418 00
Earnings before interest and taxes	-14'270.0	44'247.45
Financial expenses		
Interests paid	-16.9	95 -97.25
Bank charges	-5'430.8	-3'478.69
Foreign exchange loss	-20'067.4	-10'598.02
Total financial expenses	-25'515.1	8 -14'173.96
Earnings before taxes	-39'785.2	0 30'073.49
Prior-period and extraordinary income and expenses		
Others income	862.7	75 1'355.91
Taxes on previous year	2'610.6	1'359.98
Total pior-period income and expenses	3'473.4	2'715.89
Result before taxes	-36'311.7	9 32'789.38
Local taxes	-19'841.2	-19'508.32
Net years the years	E014E2 0	E 10/001.00

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 on the basis of the following elements:

Foreign currency translation

Assets and liabilities in foreign currencies are translated into US Dollar at the exchange rate in effect at the balance sheet date. Transactions in foreign currencies are translated into US Dollar 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.

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 2022 the liability to the pension scheme amounted to USD 4'894.63 (31 December 2021: USD 10'575.57).

Explanations of income and expenses statement

3.1 Donations carryover to the next year

The amount of USD 82'251.16 (PATH for USD 69'776.17 and PSPT for USD 12'474.99) was unused by 31st December 2022 and therefore deferred as carryover to be disbursed in 2023, 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.

3.2 Loss on members contributions

A provision on loss on members contributions for an amount of USD 15'000 has been booked for the year 2022.

4. General comments

1. DCVMN annual revenue from memberships, donations and financial gains in 2022 increased by 69%, to USD 1'295'742.35 before carryover, and before the variation on the provision on members contributions, from USD 767'761.31, in 2021. This is mainly related to increase partnerships and donations, as compared to 2021.

2. Membership status as of December 2022 indicated that there were 43 members, of which 19 were full members (with WHO PQed vaccines). In 2022 no member left the network and all but one member settled membership contributions.

3. The Network's activities and interim financial statements (up to Q3/2022) were presented by the Treasurer, on behalf of the Executive Committee, to the General Assembly of members on 20th October 2022.

4. The Board of members proposed budget for 2023 approved by the members assembly is targeted at USD 1'332'500 for DCVMN Office and USD 1'115'458 for grants. - income and ca. USD 1'469'874 for DCVMN Office and USD 1'260'000.- on grants for expenses, which includes carryover funds from donors.

5. The income budget for 2023, was based on the assumptions below:

a) a pledge of USD 1'000'000.-, allocated for training and related activities in 2023.

b) the membership contributions expected to increase to USD 915'000 (USD 561'000 in 2021).-. The funds received from members are dedicated to administrative operations including secretariat, rental, IT, supplies communication and staff salaries. c) continuous corporate sponsorship contributions estimated at ca. 220'000.- USD, for workshops and AGM.

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

6. 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 Board of members, as well as by donors and local authorities, for financial review and assessment.



1. DCVMN Board Structure 2020-23

The DCVMN Board[26] is composed of seven elected members with skills and experiences to provide governance oversight to the DCVMN secretariat, through the newly appointed Chief Executive Officer, Mr. Rajinder Kumar Suri. All Board members act on a voluntary, non-remunerated basis. The DCVMN Board held 9 formal governance meetings, on virtual platform, on the following dates: 19th January, 8th February, 15th March, 5th April, 10th May, 20th June, 12th July, 16th August, 19th October, with pre-set agenda and relevant documents circulated in advance to facilitate informed decisions. Minutes to the formal virtual meetings are accessible to all members to consult at https://dcvmn.org/board-meeting-minutes/. In addition, the Board had 3 confidential meetings with CEO in September, November and December.

Role	Name	Affiliation	Attendance out of 9 virtual meetings in 2021
Chair	Mr. Sai D. Prasad	Bharat Biotech	6
Co-chair	Mr. Patrick Tippoo	Biovac	8
Treasurer	Mr. Fernando Lobos	Sinergium	6
Member	Ms. Lingjiang Yang	CNBG of Sinopharm	9
Member	Mr. Adriansjah Azhari	BioFarma	9
Member	Mr. Tiago Rocca	Butantan	9
Member [27]	Ms. Wendy Huang	Innovax	3
CEO (non-voting)	Mr. Rajinder Kumar Suri	DCVMN International	9

2. Donors Advisory Committee

The Donors Advisory Committee[28] (DAC) advises DCVMN on donor funded activities, and has no executive role. As a strictly advisory, non-governing body, the DAC does not have either decision-making authority or fiduciary responsibilities. It is composed by three DCVMN members and four external advisers from PATH, BMGF and NIIMBL, who are supporting and guiding the Network on principles, technical and scientific activities for member manufacturers, e.g. training programs. Members are appointed by the Executive Committee according to advice and support requirements. Appointment duration is dependent on the Advisory Committee needs and individual availability. The Advisory Committee held 4 virtual meetings in 2022 (March 2nd, June 15th, September 7th and December 9th).

3. DCVMN Secretariat Structure 2022



Secretariat Organogram 2022

Acknowledgements

We are grateful for our corporate sponsors 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.



We thank the Bill and Melinda Gates Foundation and PATH for a grant to DCVMN under sub agreement no. 01705668-COL for supporting the professional training programs, SII & PATH for supporting the Annual General Meeting 2022.





Important Note: The views expressed in this publication do not necessarily represent decisions or policies of any institutions mentioned or with which the Network is associated.



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