dcvmn

Developing Countries Vaccine Manufacturers Network

ANNUAL REPORT 2021

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 2021.

Since the founding of the DCVMN in 2000, the network has steadily grown to include 42 member companies of which 16 members having WHO Pre-Qualified vaccines. Our member companies range across 15 countries in the world and are responsible for >60% of the vaccine supplies for LIC's and MIC's.

This past year however, has been even more challenging than the previous years. While the SARS-CoV-2 virus continues to impact all our lives, members within the network and the secretariat have continued their strong work to fuel the strategic vision set out by the DCVMN Board. I would like to take this opportunity to present some of the key advancements made towards the strategic vision:

1. Our Executive Committee has now officially been restructured to function as a Board of the Network and the Secretariat is now being led by the first CEO for the network, Mr. Rajinder K. Suri.

2. We have worked towards developing and hiring several subject matter experts from within the network and from external sources, in order to support with the smooth functioning of our various Board committees, sub-committees and working groups.

3. We have had increased member involvement within (COVID-19 committee, RMP Project etc.) and outside the network (CEPI Working Groups, ACT-A & COVAX manufacturing task force leadership team, interaction between Working Groups and industry stakeholders etc.).

4. Our secretariat and subject matter experts in collaboration with our membership have successfully published five peer-reviewed publications during 2020-21. These publications cover topics such as implementation of traceability standards, advancing innovation from DCVMs, challenges with combating the pandemic from a DCVM perspective, and finally the technical capabilities within the DCVMN.

5. Finally, various members within the network have taken on the fight against the SARS-CoV-2 virus and have established partnerships with member companies and with external companies towards this great cause. Till date over 15 manufacturers have licensed vaccines for COVID-19, with ~7 manufacturers having innovative novel vaccines against the SARS-CoV-2 virus.

All these advances have clearly shown that our network stands strong and is willing to take the necessary steps in order to improve access to effective and affordable vaccines across the globe. I congratulate all members of our network and the secretariat involved in achieving these goals.

As we continue our journey in 2022, I would like to reiterate that good governance is at the heart of all successful organizations. We must push towards achieving our goals while maintaining legal and ethical standards throughout.

On behalf of the Board, I would like to say that we will ensure to continue to build on the strategic vision and continue to develop the image that stakeholders, regulators and the vaccine industry as a community can rely on the DCVMN as an essential piece to the supply of good quality vaccines.

Thank you, and wishing you all a safe and successful year ahead!

SAI D. PRASAD

DCVMN Board Chair

MESSAGE FROM THE CEO

Change is the only thing constant in today's dynamic World!

The unprecedented COVID-19 Pandemic taught us lessons which we would have never even imagined before, newer ways to live and newer ways to work!! The biggest among them being collaboration!!!

DCVMN member companies responded to the COVID-19 challenge by innovating, developing, manufacturing and rolling out over 6 billion doses in 2021 itself, ~ 60% of global production.

DCVMN is now gearing for an orbital change. We are confident that DCVMN will rise to the occasion in these testing times with a young team of talented professionals who are determined to work shoulder to shoulder with member companies and all stakeholders including the International public health organizations like WHO, GAVI, CEPI, UNICEF and PATH among several others in collaboration with BMGF, NIIMBL, CHAI, R2R and industry associations like IFPMA and BIO.

Going forward in 2022 there are three clear strategic priorities to focus on:

1. Collaborate to work towards achieving vaccine equity

2. Help identify areas of immediate concern in Africa, work with like-minded organizations and develop mitigation strategies

3. Upgrade and hone skills & knowledge of member companies in all key functions as a step forward in Pandemic preparedness

Reflecting the culture of change, we have made a maiden attempt to bring a change in the annual report as well!

Looking forward to support you better!!

RAJINDER SURI

CEO-DCVMN

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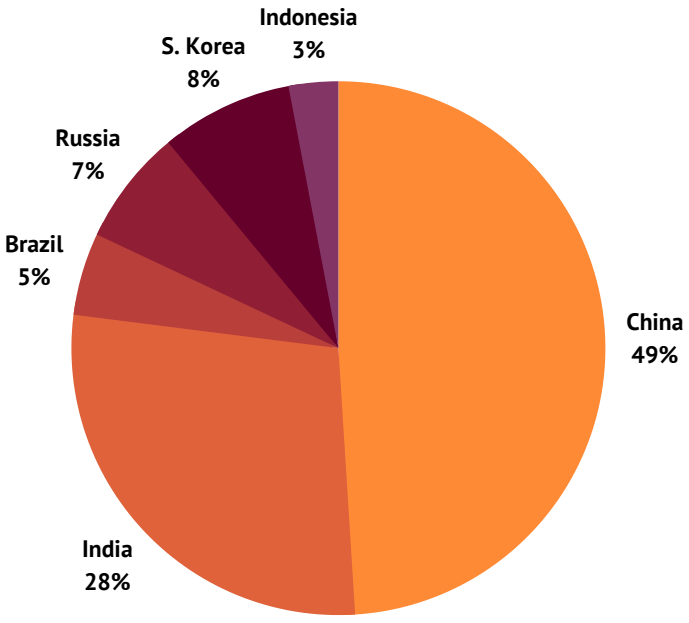
About DCVMN

AN UNPRECEDENTED YEAR

The pandemic exposed deep inequalities that have existed for years and had its hardest impact on the poorest countries, communities and those already disadvantaged. Inequitable access to COVID-19 vaccines further highlighted the disparity between the Global North and Global South. Nevertheless, in 2021, the industry joined vaccine efforts which resulted in the largest immunization campaign in human history. After just one year since the first COVID-19 vaccine was administered, vaccine makers including biotechnology firms, developing and developed country manufacturers say voluntary collaboration to share innovation has been a key enabler for manufacturing output to reach 11.2 billion doses supplied by December 2021.

Over 11 billion COVID-19 vaccines produced globally in 2021

DCVM's Estimated Production of COVID-19 Vaccines 2021



While the current output from vaccine manufacturers is theoretically enough to vaccinate everyone, urgent, concrete measures are needed to support the hoped-for surge in COVID-19 vaccine uptake in countries with currently low vaccination rates. The historic manufacturing scale up is overshadowed by a shared concern that COVID-19 vaccines are not reaching all who need them. For better pandemic preparedness we will require more and better vaccine distribution and innovation in the future.

In 2021, vaccine manufacturers 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 such as Omicron, and on future pandemics.

More information at: https://www.dcvmn.org/IMG/pdf/bio_dcvmn_ifpma_covid-19_press_release_16december2021.pdf; for independent data see https://www.dcvmn.org/IMG/pdf/airfinity_covid-19_intel_report_16december2021.pdf.pdf; https://www.unicef.org/supply/covid-19-vaccine-market-dashboard

1st

DCVM VACCINE

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

~60%

Of the global production of COVID-19 vaccines are from DCVMN member manufacturers.

1st

VACCINE TO REACH GHANA

On February 25th 2021, the vaccine was supplied by a DCVMN member to accelerate equitable access to COVID-19 vaccines in low-income countries.

60%

OF THE WORLD'S POPULATION

Has received at least one dose of a COVID-19 vaccine.

MAJOR TECHNOLOGY TRANSFERS WITH DCVMS

From Multinational Corporations to DCVMs

AstraZeneca, UK
- Serum Institute of India, India
- SK Bio, South Korea
- Bio FioCruz, Brazil
- Shenzhen Kangtai, China

Jansen (J&J), USA
- Biological E., India
- Aspen Pharmacare, South Africa

Pfizer, USA
- BioVac, South Africa

From DCVMs to DCVMs

Sinovac, China
- Butantan, Brazil
- PT Bio Farma, Indonesia
- Pharmaniaga, Malaysia

Sinopharm, China
- PT Kimia Farma, Indonesia
- G-42 Dubai, UAE

Bharat Biotech, India
- Indian Immunologicals, India

DCVMN AND GLOBAL INDUSTRY SCORE CARD

0 to >11 billion doses

World wide in 12 months

~60%

Contribution of the world wide doses coming from DCVMs

WHO WE ARE

The Developing Countries Vaccine Manufacturers Network (DCVMN) is a voluntary public health-driven alliance of 42 vaccine manufacturers from developing countries, firmly engaged in innovation, research, development, manufacturing and supply of high-quality 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 availability of high quality vaccines produced in developing countries. It works to strengthen vaccine manufacturers through the provision of information programs and professional training on technological and production improvements and new research on vaccine manufacturing. DCVMN also encourages technology transfer initiatives and educating the public about the availability of safe and effective vaccines from developing world manufacturers and related programs.

Vision

To protect people of all age groups in LMICs and emerging economies against dreaded infectious diseases by innovating, developing, manufacturing, and providing a consistent and sustainable supply of quality vaccines at an affordable price to accelerate and reach the goal of vaccine equity worldwide.

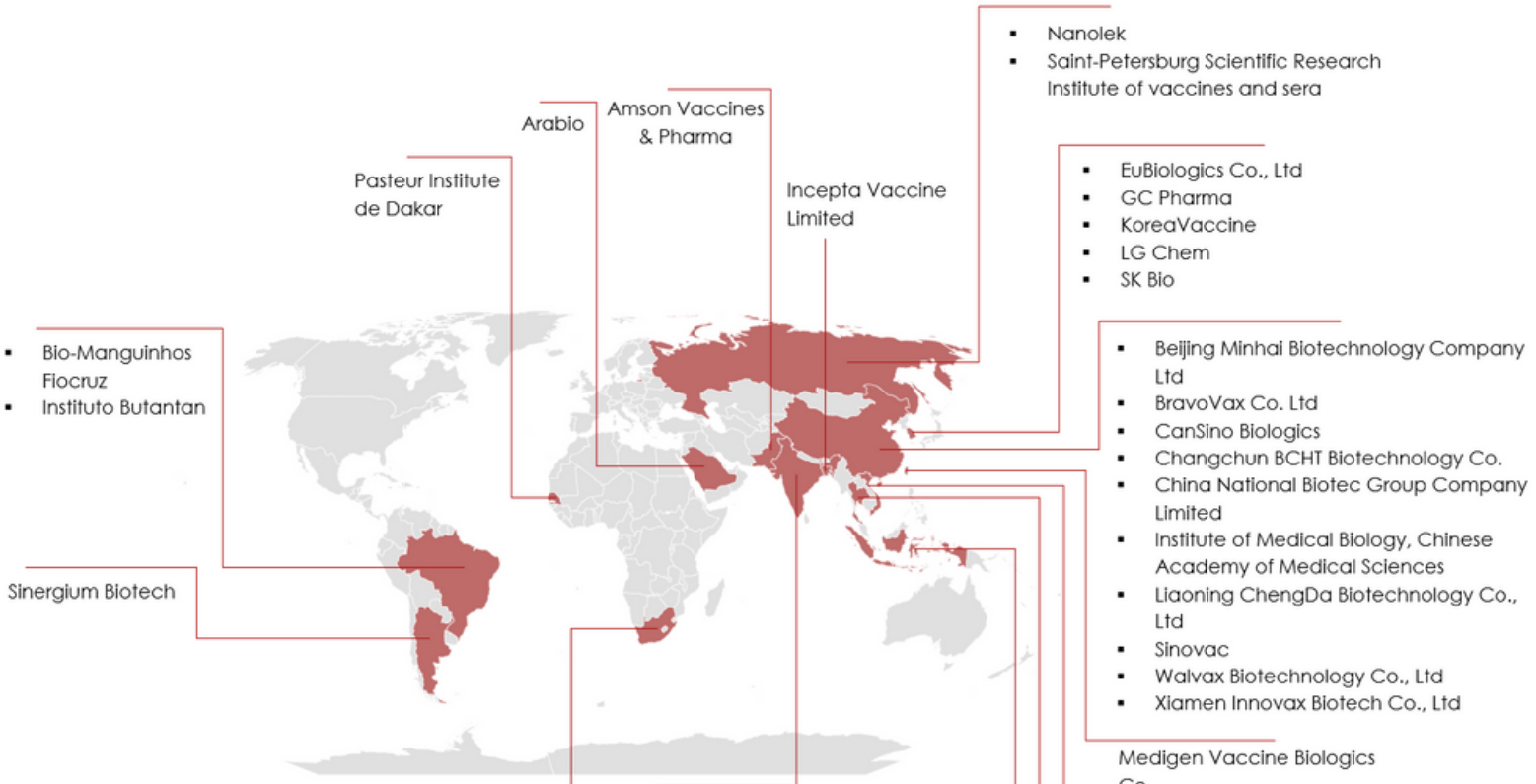
Mission

To foster a voluntary, public health driven alliance of vaccine manufacturers from developing countries to develop collaborations and communication amongst them, with other industry associations and academia to encourage their research, development, production and roll-out efforts to meet vaccine needs and strive for international recognition and attaining the status of WHO pre-qualification for a range of vaccines.

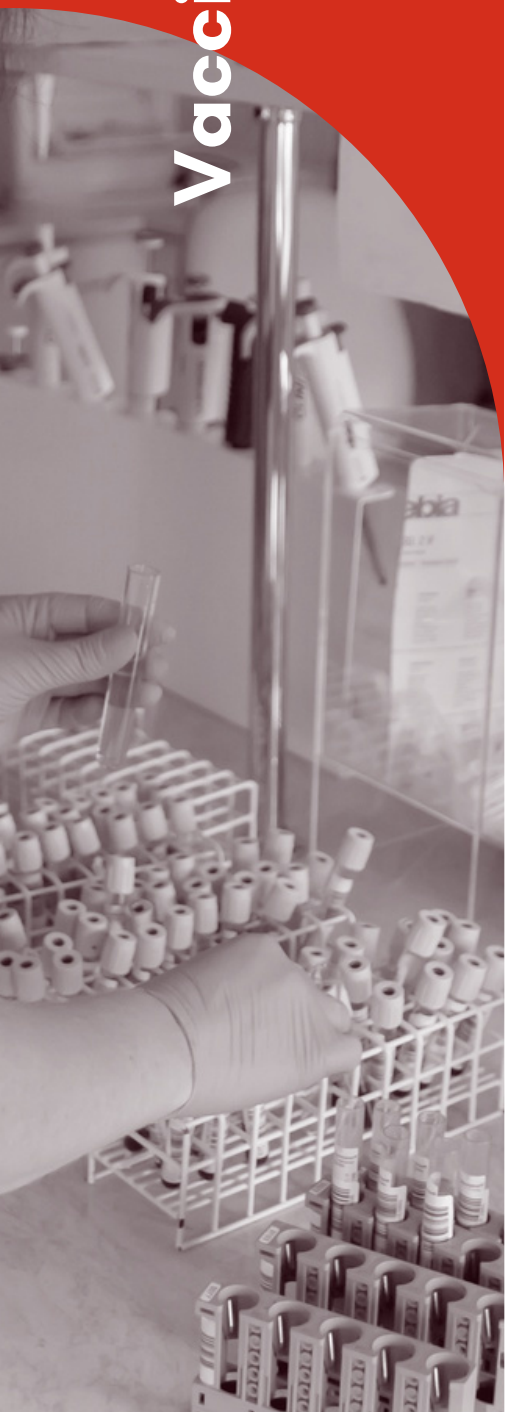
Strategic Objectives

- 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.

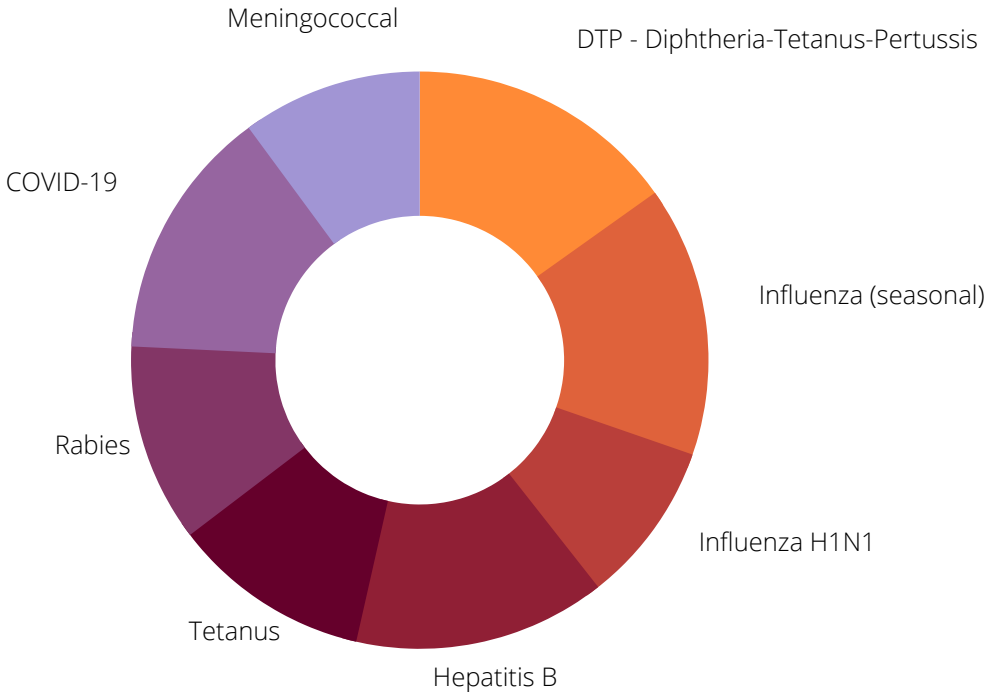
THE MEMBER MANUFACTURERS OF DCVMN



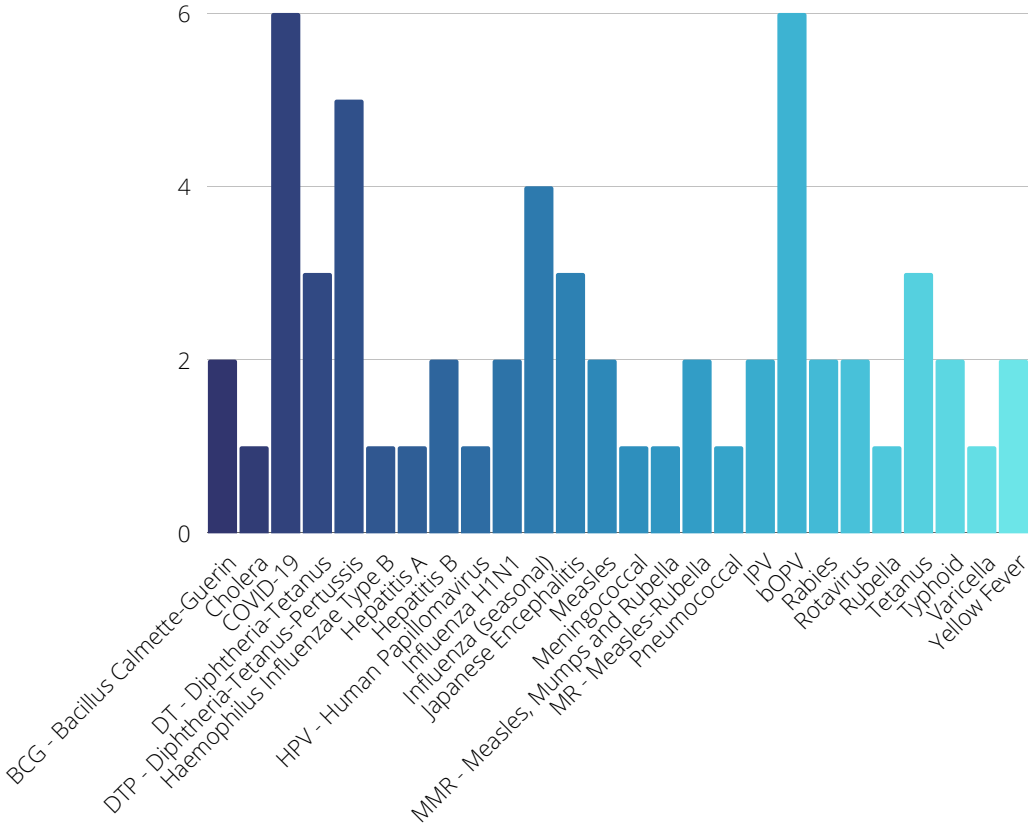
Vaccines Manufactured by Members



Most number of manufacturers for a vaccine as of 2021



Number of vaccines with WHO Emergency Use Listing and Prequalification as of 2021



2022 DCVMN Objectives and Strategies

Objectives

- To maximize vaccine reach by leveraging regulatory reliance mechanisms;
- To help augment quality standards;
- To increase voice share of DCVMN in international stakeholders;
- To help increase wallet share of member companies from the donor agencies;
- To ensure rapid and successful technology transfers leveraging new vaccine platforms.

Strategies

- Communication and Brand Strategy: Harnessing COVID-19 strengths to build brand equity through high level representation in global forums;
- Increase active collaboration with international agencies like WHO, GAVI, CEPI, PATH, BMGF, NIIMBL, CHAI [1] and several others;
- Through Healthy Industry Framework (HIF): Bilateral & Multilateral partnerships & innovation;
- Through collaboration with industry associations like IFPMA, BIO & others;
- Use specialized training in Technology Transfer by Hilleman Labs, IVI and others supported by PATH/ BMGF etc.

[1] WHO – World Health Organization
GAVI – Gavi, The Vaccine Alliance
CEPI – Coalition for Epidemic Preparedness Innovations
BMGF – Bill & Melinda Gates Foundation
NIIMBL – National Institute for Innovation in Manufacturing Biopharmaceuticals
CHAI – Clinton Health Access Initiative

DCVMN Members' Successes in Vaccine Development and Supply in 2021

7 DCVMN members partnered with multinational companies to manufacture and supply of COVID-19 vaccines.

Instituto Butantan's **Influenza** vaccine and Innovax's **HPV** vaccines entered the list of vaccines prequalified by WHO.

WHO lists **5** COVID-19 vaccines from DCVMN members for Emergency Use Listing (EUL)[2].

6 COVID-19 vaccines from DCVMN members have been granted Emergency Use Authorization (EUA) by numerous countries.

4 Member manufacturers signed agreements with Gavi for immediate COVID-19 vaccines supply to COVAX.

[2] WHO's Emergency Use Listing mechanism procures the assurance that the vaccine meets international standards for safety, efficacy and manufacturing during public health emergencies, and allows countries to expedite their own regulatory approval to import and administer COVID-19 vaccines; it is also a prerequisite for COVAX Facility financing and supply.

COVID-19 Vaccines Developed and Supplied by DCVMN

INDIA REGULATOR GRANTS EMERGENCY USE FOR COVID-19 VACCINES MANUFACTURED BY SII

Pune, 06th January 2021 - Serum Institute of India (SII), the world's largest vaccine manufacturer, partnered with AstraZeneca, for manufacturing and suppling the COVID-19 vaccine to the Indian Government but also to a large number of low and middle-income countries. This COVID-19 vaccine has been granted EUA for the active immunization of adults in India, Argentina, Dominican Republic, El Salvador, Mexico and Morocco.

SINOVAC BIOTECH COVID-19 VACCINE AUTHORIZED IN INDONESIA FOR EMERGENCY USE

Jakarta, 14th January 2021 - Indonesia approved Sinovac Biotech COVID-19 vaccine for emergency use, paving the way to start its inoculation program. WHO determined that this vaccine has an efficacy of 51% against symptomatic SARS-CoV-2 infection, 100% against severe COVID-19, and 100% against hospitalization starting 14 days after receiving the second dose. The emergency use authorization in Indonesia is the first for Sinovac's vaccine outside of China.

BRAZIL AUTHORIZES AND ROLLS OUT SINOVAC VACCINE

Brasilia, 17th January 2021 – The Brazilian Regulatory Agency, ANVISA, authorized the emergency use of vaccines from Oxford-AstraZeneca and China's Sinovac, doses of which will be distributed by local public partners, Fiocruz and Butantan, in all 27 states. About six million doses of the Sinovac-manufactured CoronaVac and up to an additional 40 million doses filled in Brazil by Butantan have been approved. Two Brazilian companies have been given authorization to manufacture the vaccines locally.

WHO LISTS TWO COVID-19 VACCINES FROM DCVMN MEMBERS FOR EMERGENCY USE

Geneva, 15th February 2021 - WHO issued an EUL for the COVID-19 vaccines produced by SKBio (Republic of Korea) and the Serum Institute of India (India), two versions of the AstraZeneca/Oxford vaccine, to be rolled out globally through the COVAX Facility. Through this contribution to the COVAX facility, Dr Mariângela Simão - WHO Assistant-Director General for Access to Medicines and Health Products - stated that countries with no access to COVID-19 vaccines to date will finally be able to start vaccinating their health workers and populations at risk.

WHO LISTS SINOPHARM/CNBG COVID-19 VACCINE FOR EMERGENCY USE AND ISSUES INTERIM POLICY RECOMMENDATIONS

Geneva, 07th May 2021 - The Sinopharm COVID-19 vaccine was added to WHO EUL, providing the green light for this vaccine to be rolled out globally.

The Sinopharm vaccine is produced by Beijing Bio-Institute of Biological Products Co Ltd., subsidiary of China National Biotec Group (CNBG). Dr Mariângela Simão, further recognized the added potential of this vaccine in combatting vaccine inequity.

PANACEA BIOTEC ANNOUNCES MANUFACTURING LICENSE TO PRODUCE THE COVID-19 VACCINE SPUTNIK V IN INDIA

New Delhi, 04th July 2021 – Panacea Biotec, one of the leading vaccine and pharmaceutical producers in India, received manufacturing license from Drug Controller General of India (DCGI) for Sputnik V vaccine against COVID-19, pursuant to its collaboration with Russian Direct Investment Fund. The batches produced at Panacea Biotec's facilities at Baddi, Himachal, have successfully passed all the checks for quality parameters both at the Gamaleya Center in Russia and at the Central Drug Laboratory, Kasauli, in India. Sputnik V was registered in India under the emergency use authorization procedure on April 12, 2021 and vaccination against Covid-19 with the Russian vaccine started on May 14, 2021.

WHO VALIDATES SINOVAC-CORONAVAC VACCINE FOR EMERGENCY USE

Geneva, 01st June 2021 – The Sinovac COVID-19 vaccine added to WHO EUL. In the case of the Sinovac-CoronaVac vaccine, the WHO assessment included onsite inspections of the production facility. The Sinovac-CoronaVac product is an inactivated vaccine. Initially, a sample of SARS-CoV-2 from China was used to grow large quantities of the virus using Vero cells in culture. From then on, the viruses are soaked in beta-propiolactone, which deactivates them, while leaving other particles intact. The resulting inactivated viruses are formulated with an aluminum-based adjuvant. Its easy storage requirements make it very manageable and particularly suitable for low-resource settings.

SINOPHARM AND SINOVAC SIGN AGREEMENTS WITH GAVI FOR IMMEDIATE COVID-19 VACCINES SUPPLY TO COVAX

Geneva, 12th July 2021 – Gavi, the Vaccine Alliance, signed advance purchase agreements (APAs) with Sinopharm and Sinovac for inactivated virus vaccines against COVID-19. The agreements will begin to make 110 million doses immediately available to participants of the COVAX Facility, with options for additional doses. The Sinopharm APA enables Q3 supply 60 million doses that will be made available from July through October 2021. The Sinovac APA also enables Q3 supply of 50 million doses to be made available from July through September 2021.

BIOVAC TO HELP MAKE PFIZER/BIONTECH COVID VACCINE

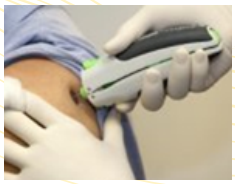
South Africa, 21st July 2021 - Pfizer (PFE.N) and BioNTech (22UAy.DE) struck a deal for South Africa's Biovac Institute to help manufacture around 100 million doses a year of their COVID-19 vaccine for the African Union. It would consist of the final stages of manufacturing, to "fill and finish" the vaccine, where the product is processed and put into vials. It does not cover the processes of mRNA drug substance production, which Pfizer and BioNTech will do at their own facilities. The agreement made Biovac - a joint venture between the South African government and private sector partners - one of the few companies in Africa processing and distributing COVID-19 vaccines, and the first to do so using the mRNA technology.

BIOMANGUINHOS AND SINERGIUM SELECTED BY PAHO TO DEVELOP COVID-19 MRNA VACCINES

Washington DC, 21st September 2021 –PAHO selected Sinergium Biotech (Argentina) and Bio-Manguinhos (Brazil) as regional hubs for the development and production of mRNA-based vaccines in Latin America in a bid to tackle COVID-19 and future infectious-disease challenges.

The Bio-Manguinhos Institute of Technology on Immunobiologicals at the Oswaldo Cruz Foundation (FIOCRUZ) has a long tradition in vaccine manufacturing and has made promising advances in the development of an innovative mRNA vaccine against COVID-19. Sinergium Biotech, a private sector biopharmaceutical company, will partner with pharmaceutical mAbxience, to develop and manufacture active vaccine ingredients. The two companies have extensive experience in the production and development of vaccines and biotechnological medicines.

WORLD'S FIRST PLASMID-BASED DNA COVID-19 VACCINE RECEIVED EMERGENCY USE AUTHORIZATION IN INDIA



Ahmedabad, 20th August 2021 - Zydus Cadila received the EUA from the DCGI for ZyCoV-D, the world's first Plasmid DNA vaccine for COVID-19.

This vaccine is exclusively administered using the PharmaJet Tropis® Needle-free Injection System. During phase 3 clinical trials, ZyCoV-D showed robust immunogenicity, tolerability, and safety. Unlike most COVID-19 vaccines, which need two doses or even a single dose, ZyCoV-D is administered in three doses.

BHARAT'S COVID-19 VACCINE GRANTED EUL BY THE WHO

Hyderabad, 10th November, 2021 - The WHO listed India's COVID-19 vaccine, Covaxin, made by Bharat Biotech for emergency use. The WHO's expert panel, which authorises emergency use internationally, stated that the vaccine was recommended for use in all age groups 18 and above. This vaccine is a whole virion inactivated vaccine against SARS-CoV2, developed by Bharat Biotech in partnership with Indian state research bodies, ICMR and NIV. To date India has administered more than 110 million Covaxin doses to local population, and has also been exported.

SK BIOSCIENCE EXPANDS PARTNERSHIP WITH CEPI TO DEVELOP A 'VARIANT-PROOF' VACCINE AGAINST SARS-COV AND SARS-COV-2 VARIANTS

Seoul and Oslo, 21st December 2021 - SK bioscience and the CEPI, announced an expanded partnership to develop a 'variant-proof' vaccine candidate against the group of viruses containing SARS-CoV and SARS-CoV-2. CEPI will provide up to USD $50 million to support the development of a vaccine candidate based on SK's nanoparticle vaccine platform to elicit immune responses that could protect against variants of both SARS-CoV, SARS-CoV-2, and other similar viruses. The funding will support immunogen design, preclinical studies, Phase I/II clinical trials, production of necessary clinical trial material, and process and analytical development.

Other Essential Vaccine Advancements by DCVMN Manufacturers

BUTANTAN'S INFLUENZA VACCINE ENTERS LIST OF VACCINES PREQUALIFIED BY WHO

Geneva, 26th April 2021 – The trivalent influenza (flu) vaccine manufactured by Instituto Butantan (Brazil) was included in the list of vaccines prequalified by the WHO. Consequently, the Butantan flu vaccine can be supplied globally through the UN procurement agencies, such as UNICEF and PAHO Revolving Fund. The WHO prequalification represents a recognition of Butantan's good manufacturing practices, the production processes and quality control, as well as clinical, pharmacovigilance procedures, involved in the manufacturing and registration of vaccines. Butantan is the largest producer of influenza vaccines in Latin America, with 80 million doses available each year, made by the technology of inoculation of embryonated eggs.

NEW HPV VACCINE FROM INNOVAX RECEIVES WHO PREQUALIFICATION

Xiamen, 14th October, 2021 - A new vaccine against human papillomavirus (HPV), manufactured by Xiamen Innovax Biotech CO., LTD., a wholly owned subsidiary of Beijing Wantai Biological Pharmaceutical Co., LTD., received prequalification by the WHO. The vaccine, named Cecolin® is designed to protect against HPV types 16 and 18. WHO prequalification allows Cecolin®, which is licensed for use in China, to be procured by UN agencies and Gavi, and facilitates it to be registered in other countries—a critical step in expanding vaccine access.

NEW TETRAVALENT INFLUENZA VACCINE REGISTERED BY SAINT-PETERSBURG RESEARCH INSTITUTE OF VACCINES AND SERUMS

Moscow, 04th August 2021 - The Ministry of Health of the Russian Federation granted marketing authorization for a new tetravalent influenza vaccine manufactured by the Saint-Petersburg Scientific Research Institute of Vaccines and Serums of the FMBA of Russia. The new vaccine forms the immunity against four existing influenza virus strains in accordance with the WHO recommendations. Flu-M vaccines are manufactured according to the original technology, which ensures less content of chicken protein as compared to the foreign equivalents, which is particularly important for allergic people. The Institute's manufacturing capacities in Krasnoe Selo are able to produce approximately 20 million doses of tetravalent vaccine per year.

DCVMN Training Provided to Ensure Consistent and Sustainable Supply of Quality Vaccines

In 2021, DCVMN offered its members scientific and technical learning opportunities, based on individual, self-paced e-learning courses, as well as interactive professional training workshops, in a fully virtual format, due to travel limitations and social distancing measures to control the spread of COVID-19.

Cumulative number of e-training enrollments and cumulative number e-certificates achieved from 2017 to 2021. Platform available at https://moodle.dcvmn.net

E-LEARNING

In December 2016, DCVMN launched its e-learning platform, offering self-paced, flexible learning tools to strengthen vaccine manufacturers' knowledge to produce safe, effective, and affordable vaccines for all people. E-courses are openly accessible for free at *https://moodle.dcvmn.net/*, upon registration. At the end of each e-course, participants scoring 80% or more in the quiz can download a customized e-certificate of achievement. By December 2021, the DCVMN e-learning platform offered 25 e-courses to professionals of its member companies, with three new e-learning courses added to the platform in 2021. Since 2016, 4801 enrollments were recorded in the e-learning courses, of which 2247 achieved certificates (see figure in previous page). In 2021, nearly 1000 enrolled to the DCVMN e-learning courses and 378 earned certificates.

INTERACTIVE E-WORKSHOPS

Since 2013, DCVMN has organized interactive technical training workshops[3], on topics of common interest, for the continuing education of professionals from its member companies.

Throughout 2021, DCVMN organized a series of meetings and workshops, mainly related to the four focus areas of work: Regulatory Affairs, Pharmacovigilance (PV) & Risk Management, Supply Chain & Traceability, and QC (3Rs and PSPT), which were held in an interactive virtual format[4].

Around 1000 participants, attended the various e-workshops and expert Working Group meetings, held regularly throughout the year, to foster knowledge through sharing and open discussions on best-practices. In total, 48 workshops were convened and facilitated by DCVMN secretariat in 2021, as shown in the table below. In addition to internal DCVMN meetings, member companies also participated in an array of innumerous other meetings, workshops, and training, organized by WHO, CEPI, GAVI, UNICEF, and other international stakeholders.

Area of Work /Topic	# of workshops & WG meetings	Comments
Regulatory Working Group and Risk Management Plan ([5])	10	6x RMP workshops plus 3x WG meetings
Pharmacovigilance Working Group and Vaccine Safety ([6])	14	9x PV training workshops plus 5x WG meetings
Supply Chain Working Group and Traceability ([7])	7	4x Traceability workshops plus 3x Supply Chain WG meetings and 1x workshop on vaccine stockpiles
QC (3Rs Working Group and PSPT) ([8])	17	13x PSPT technical workshops plus 4x 3Rs WG meetings
Total	**48**	**WG meetings & Workshops**

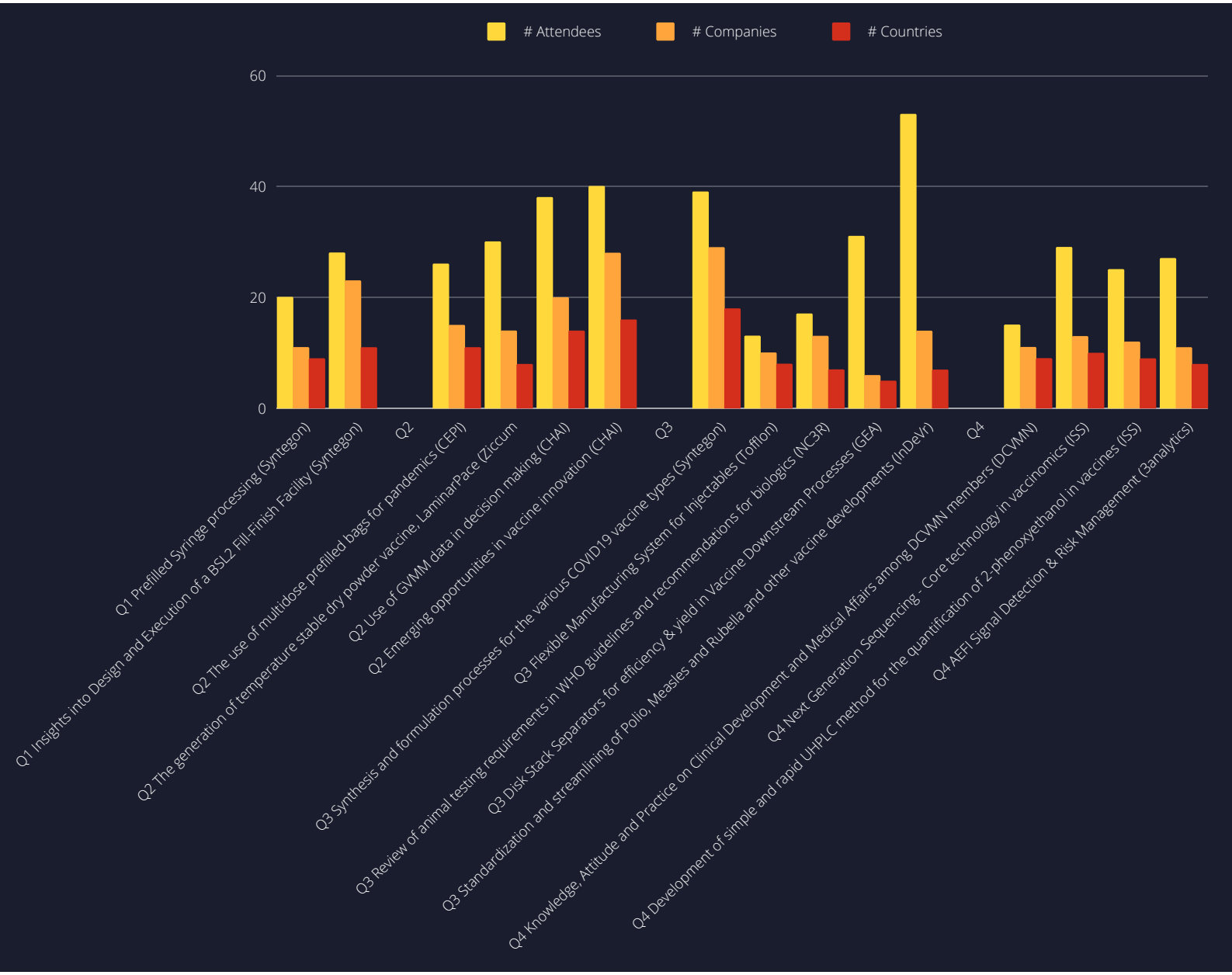
[3] Training materials are openly available at https://www.dcvmn.org/-Training-workshop-materials-88-.
[4] https://www.dcvmn.org/-expert-working-groups-
[5] https://www.dcvmn.org/Past-Regulatory-WG-meetings-dates; https://www.dcvmn.org/Past-meetings-dates-637
[6] https://www.dcvmn.org/Past-meetings-dates-414; https://www.dcvmn.org/Other-materials-and-templates-484
[7] https://www.dcvmn.org/Past-Supply-Chain-WG-meetings-dates; https://www.dcvmn.org/March-30-31-2021-WORKSHOP-Supply-Chain-Stockpiling; https://www.dcvmn.org/Traceability-Consortium-meeting-minutes
[8] https://www.dcvmn.org/Past-meetings-dates-400; https://www.dcvmn.org/-PSPT-consortium-57-

WEBINARS: INCREASING ACCESS TO UPDATED KNOWLEDGE AND TECHNICAL EXPERTISE

Since 2015, experts from DCVMN resource members and other organizations and sponsors have voluntarily presented webinars on innovative developments and technical topics of interest to the vaccine industry, approximately on a monthly basis. These webinars[9] continue to be a useful platform for regular information sharing with members.

In 2021, DCVMN held 18 webinars, fostering communication within the global industry about novel technologies and technical topics. Attendance is monitored by number of connections, companies and countries per session. Note that one webinar connection can represent a group of attendees. Averages in all three metrics are stable over the years, with an upward trend of ca. 20% increase in 2021.

Number of connections, companies and countries at DCVMN webinars in 2021. Note that one connection may correspond to a group of persons attending. Three webinars in Q1-2021 had no statistical data due to technical issues. Chart graciously Prepared by Mr. S.Cunden.



[9] Slides and recordings of webinars are openly available on the DCVMN website (https://www.dcvmn.org/-Webinar-materials-13-) provided speakers had agreed.

PROFESSIONAL CERTIFICATION PROGRAMS

Following a DCVMN training workshop "Fostering Regulatory Convergence Dialogue in Asia", held on 25th March 2019, in Singapore, DCVMN Secretariat sought to understand about the scope of the Center of Regulatory Excellence (CoRE) at the National University of Singapore (NUS) and identified areas for collaboration in regulatory professional training and certification in 2020.

To build a regulatory knowledge basis and excellence throughout the network, this year DCVMN sponsored the training fees for 36 employees of member companies, chosen through a selection criterion following their nomination, which participated in e-training courses and e-workshops on Pharmaceutical Regulation, Biosimilars & Biotherapeutics, Pharmacovigilance and Clinical & Medical Affairs at the National University of Singapore, achieving personal certification on various subject matters. This professional education is aimed at facilitating and improving regulatory as well as clinical and medical best practices among professionals employed by the vaccine industry in developing countries, to ensure adequate assessment of products manufactured in emerging countries. This professional education program has been supported by generous philanthropic and non-profit donors[10] and is planned to continue in 2022 with the addition of a new program - Technology Transfer Training at Hilleman Labs.

dcvmn
Developing Countries Vaccine Manufacturers Network

NUS National University of Singapore

CoRE
Centre of Regulatory Excellence @ Duke-NUS Medical School

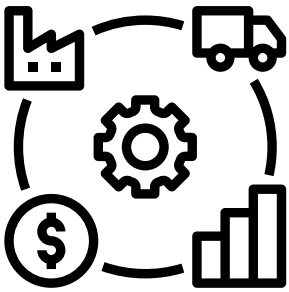
LOOKING FORWARD: VIRTUAL REALITY

In 2021, DCVMN developed further the Virtual Reality (VR) training tools, related to laboratory and facility hands-on experiences. Specifically, one VR tool related to the preparation of human peripheral blood mononuclear cells (PBMCs), for use in various in vitro testing, and one complementary VR tool for performing the Monocyte Activation Test (MAT) to assess in vitro pyrogenicity of vaccine preparations. The VR software can to be installed in VR devices for people to conduct the full VR hands-on experience[11].

[10] More information at https://www.duke-nus.edu.sg/core/about
[11] https://www.dcvmn.org/-DCVMN-Virtual-Reality-Trainings-

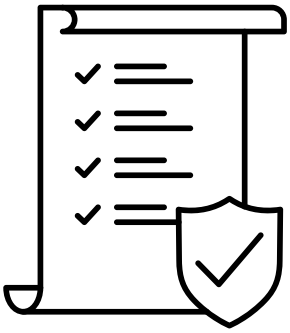
Expert Working Groups

The expert Working Groups (WGs) are formed by DCVMN member manufacturers around areas of common interest, including Supply Chain & Traceability, Regulatory Affairs, QC testing/3Rs & PSPT, Pharmacovigilance & Risk Management Plan, 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

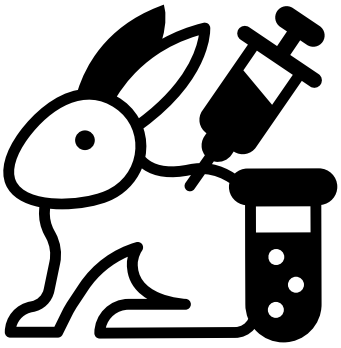
The goal of the supply chain expert group is to share best practices and find common solutions for companies to increase the efficiency and effectiveness of their vaccine supply chain through innovation in the manufacturing and distribution stages. Presently, the group focuses on tracking vaccines (traceability), 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.

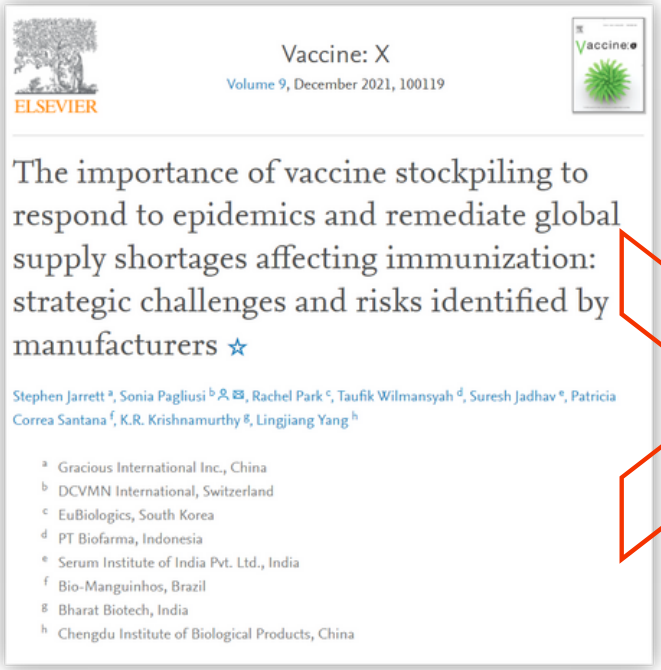
BEST-PRACTICES SUPPLY CHAIN WORKING GROUP

Based on the analyses of needs, agreed priorities, and previous discussions of the Supply Chain Working Group, a peer-reviewed publication provided members' views on the priorities to strengthen the global vaccine supply chain[12].

Two priorities were the main focus of the working group during 2021:

The first is related to the engagement of member companies in pilot studies towards the implementation of global GS1 traceability standards for the supply chain, shipping and supply of vaccines, to combat counterfeiting and enhancing safety monitoring. A Traceability Consortium was voluntarily formed by six interested member companies: BioFarma, Biological E, Bharat Biotech, CNBG, Innovax and Sinergium, with the goal of sharing knowledge and experiences on the barcoding of secondary packaging, to comply with Gavi/UNICEF shipping requirements, and on primary packaging to facilitate the supply of COVID-19 vaccines in multidose vials. Four out of the six manufacturers piloting the traceability, requested limited financial support, for planning and training aligned to GS1[13] standards. This was partially assessed by an independent review group, funded by external donors for a limited time period, to validate the tools, and it was administered by DCVMN Secretariat to accelerate the pilot studies in the barcoding of primary and secondary packaging.

The second priority is related to the importance of vaccine stockpiling to respond to epidemics and to remediate global supply shortages affecting immunization. In this context, vaccine stockpiling policies and practices were discussed in a workshop, and challenges and risks were identified by manufacturers, as outlined in a peer-reviewed publication to share views and stimulate open discussions.



[12] https://doi.org/10.1016/j.jvacx.2021.100119
[13] www.gs1.org

RISK MANAGEMENT PLANNING - REGULATORY & PHARMACOVIGILANCE JOINT PROJECT

Encouraged by inspiring discussions and achievements of 2020, such as the CRP implementation[14], the DCVMN Best Practice Working Groups on Regulatory and Pharmacovigilance shaped a joint project aimed at assisting manufacturers in learning how to prepare a robust Risk Management Plan (RMP) for a vaccine of their choice, for which they wish to achieve registration and WHO prequalification. The objective of this project is to strengthen the knowledge and capabilities of vaccine manufacturers in developing risk management plans to be submitted in parallel with Common Technical Dossiers, in order to meet the ICH E2E and EMA GVP Module V requirements.[15] RMPs are a regulatory requirement and are particularly important in the case of novel vaccines (targeting new diseases or produced using novel production platforms) with no or limited post-marketing data, such as the COVID-19 vaccines.

The project was launched in May 2021, focusing on and limited to the development of a RMP for the monitoring of safety and effectiveness of any vaccine. The project involved an active learning process (learn-by-doing), whereby learners engaged in a series of five Q&A workshops: analysis, development, revision, synthesis, and evaluation of their own plans. Eleven member companies expressed interest[16], ten voluntarily engaged in the Q&A workshop series with senior expert professionals, and nine RMPs were drafted and reviewed by the experts for comments on improvements, while respecting confidentiality. This project enabled DCVMN member companies to voluntarily established a multidisciplinary team for risk management (safety and efficacy of vaccines) to draft a RMP that met, in principle, international standards.

[14] https://www.dcvmn.org/DCVMN-manufacturers-trigger-successful-Collaborative-Registration-Procedure-CRP
[15] https://www.dcvmn.org/IMG/pdf/rmp_project_proposal.pdf
[16] https://www.dcvmn.org/Project-Participants-List

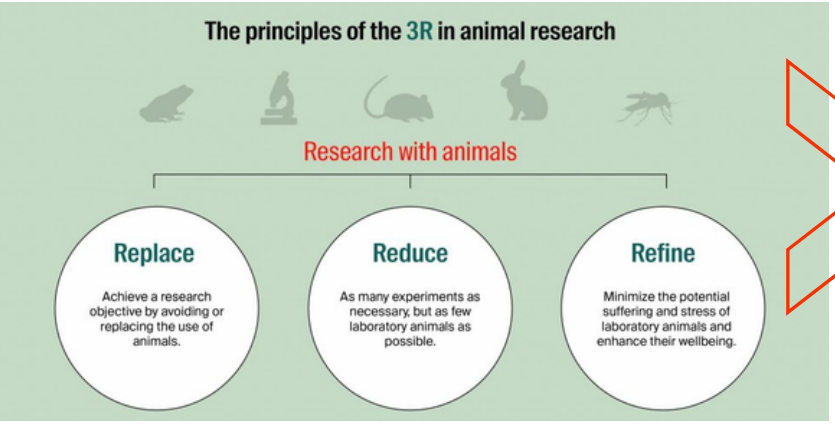
DCVMN's PROJECTS PROMOTING THE 3Rs IN VACCINE BATCH RELEASE TESTING

As part of DCVMN's effort to implement 3Rs through active participation in international dialogues to promote global regulatory alignment of vaccines testing requirements, such as deleting obsolete animal testing, the 3Rs Working Group has carried out new and already existing dedicated projects throughout 2021.

The Pertussis Serological Potency Test (PSPT) Consortium, established by DCVMN in 2020 and funded by the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), reached some important milestones within 2021. PSPT is closer to its goal than ever: to accelerate the laboratory implementation of the new testing assay - its regulatory acceptance, the reduction of animal testing which would consequently also reduce the final cost of the batches. 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. Thirteen technical workshops were organized by DCVMN secretariat to inform, train and support laboratories in all the steps of the testing activities, and a dedicated data collection platform was created for anonymized data submission. The results of the testing will be released by mid-2022.

The 3Rs Working Group provided the members with a webinar[17], an e-learning course[18] and a Virtual Reality experience to help members to familiarize with the Monocyte Activation Test (MAT), which is an alternative test to the Rabbit Pyrogenicity Test. Another training opportunity to help members to improve their Quality Control process has been offered via a workshop on Statistical Analysis of Stability Testing[19], and two webinars dedicated to the "Development of simple and rapid UHPLC method for the quantification of 2-phenoxyethanol in vaccines)" and the "Next generation sequencing – Core technology in vaccinomics"[20].

DCVMN has committed to the deletion of the Abnormal Toxicity Test, participating to the dedicated international workshop on October 14th, organized by Humane Society International, the European Federation of Pharmaceutical Industries and Associations, and the International Alliance for Biological Standardization[21]. Further commitment from DCVMN toward the implementation of 3Rs has come through its engagement in the dedicated working groups lead by the National Centre for the Replacement, Refinement & Reduction of Animals in Research - NC3Rs[22]. The NC3Rs and WHO project aims to propose the inclusion of the latest 3Rs opportunities in the WHO Technical Report Series.

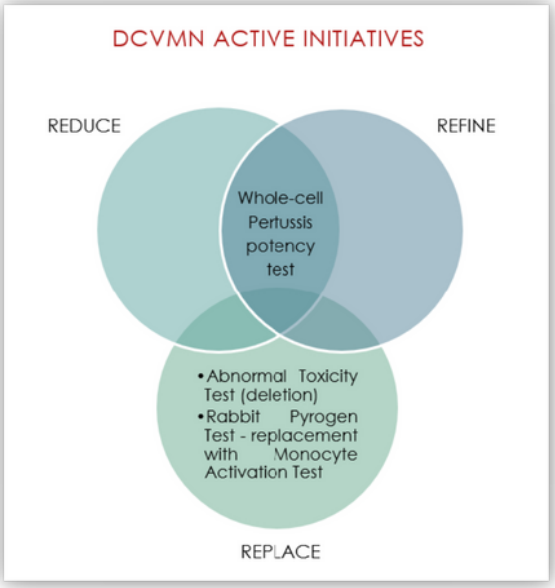


[17] https://dcvmn.org/-Webinar-materials-13- - 18 February 2021
[18] https://moodle.dcvmn.net/
[19] https://www.dcvmn.org/E-workshop-on-Statistical-Analysis-of-Stability-Testing
[20] https://www.dcvmn.org/-Webinar-materials-13- 13 and 27 October 2021.
[21] https://www.afsacollaboration.org/biologicals/att-deletion-workshop/
[22] https://nc3rs.org.uk/review-animal-use-requirements-who-biologics-guidelines

DCVMN Members' Status of the 3Rs Principles

At the end of 2020, an internal survey was carried out on the animal use and 3Rs interest within DCVMN. Among the 28 members that replied to the survey, some already have 3Rs initiatives ongoing a general interest to learn more about the opportunities to be taken. At the forefront of this effort are members in South East Asia who not only are minimizing animal testing but are employing new approaches in pyrogenicity; batch potency and safety testing. Nevertheless, more time, investments and commitment to implementing new practices is needed to see a significant decrease in animal testing for vaccine development and manufacturing. At the same time, effort should be increased to improve dialogue with regulatory authorities and promote regulatory acceptance of these new approaches.

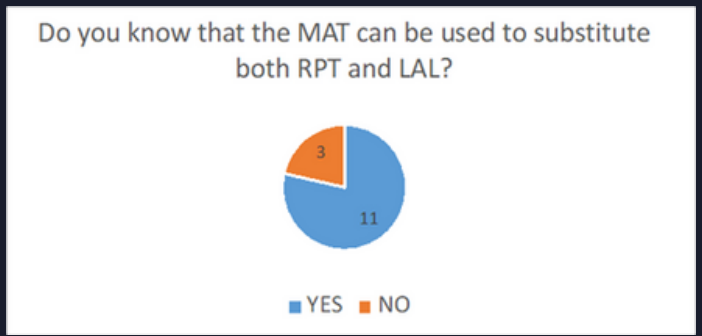
The survey results also demonstrated that further advocacy for animal testing replacement opportunities needs to be done within DCVMN to ensure that all members are knowledgeable of the alternative options.

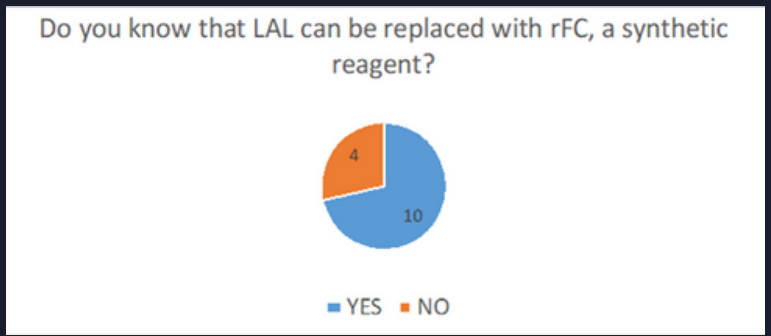


3Rs considerations to move forward:

- Consider to move to potency tests based on serology or directly to in vitro assays whenever possible – opportunities exist.
- Abnormal toxicity test is not requested anymore by WHO and removed by EU, US, Canada, India, Brazil, Argentina, Cuba, South Africa and more will follow.
- Specific toxicity for DT could be removed as well based on validated detoxification process.
- Neurovirulence testing should be addressed as well in the future using next generation sequencing techniques.
- The implementation of practices and opportunities following the 3Rs principles need to be speeded up through - more training; advance dialogue and data sharing with local, regional and international regulatory authorities and other advocacy organizations.

Figures above demonstrate two of the survey responses given by DCVMN members to Pyrogenicity testing replacement opportunities.





DCVMN Representation at Global Meetings

DCVMN SPEAKERS AT GLOBAL MEETINGS

WTO MEETING
SAI D PRASAD

CEPI - 12TH ECTMIH CORONA DAY
RAJINDER SURI

CEPI INVESTMENT CASE 2.0 LAUNCH EVENT
RAJINDER SURI

7TH ACT-A FACILITATION COUNCIL
SAI D PRASAD

GLOBAL ECONOMIC FORUM
SAI D PRASAD

WTO-COVID-19 VACCINE SUPPLY CHAIN & REGULATORY TRANSPARENCY SYMPOSIUM
RAJINDER SURI

LAUNCH OF THE INVESTMENT OPPORTUNITY FOR THE GAVI COVAX AMC
MAHIMA DATLA (GAVI BOARD REPRESENTATIVE & GAVI PPC REPRESENTATIVE FOR DCVMN) & LI MENG (SINOPHARM)

WTO-WHO HIGH-LEVEL DIALOGUE ON EXPANDING COVID-19 VACCINE MANUFACTURE TO PROMOTE EQUITABLE ACCESS
RAJINDER SURI

GLOBAL SUPPLY CHAIN AND MANUFACTURING SUMMIT
SAI D PRASAD, MAHIMA DATLA, DR. MORENA (BIOVAC), RAHMAN RUSTAN (BIOFARMA), RAJINDER SURI

DCVMN PARTICIPATION AT GLOBAL MEETINGS

WHO TECHNICAL CONSULTATION ON PANDEMIC INFLUENZA VACCINE RESPONSE
RAJINDER SURI

GAVI COVAX AMC ONE WORLD PROTECTED VIRTUAL SUMMIT CO-HOSTED BY GAI & PRIME MINISTER OF JAPAN
SAI D PRASAD & RAJINDER SURI

WHO-CEPI VACCINE MANUFACTURING WORKSHOP FOR THE WHO EASTERN - MEDITERRANEAN REGION
ADRIANSJAH AZHARI (BIOFARMA) & RAJINDER SURI

EXTRAORDINARY INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES (ICDRA)
RAHMAN RUSTAN & RAJINDER SURI

LAUNCH OF THE INVESTMENT OPPORTUNITY FOR THE GAVI COVAX AMC
SAI D PRASAD & RAJINDER SURI

PAVM MARKET DESIGN AND DEMAND INTELLIGENCE
RAJINDER SURI

22nd Annual General Meeting

VACCINES: NEW CHALLENGES, NEW PARADIGMS, NEW OPPORTUNITIES!

DCVMN held its 22nd Annual General Meeting from 19th to 21st October 2021, on a virtual platform. This year, in its General Assembly, DCVMN welcomed 2 new corporate members: Institute Pasteur de Dakar (Senegal) and CanSino Biologics (China).

Over 350 professionals from 33 countries, including 37 DCVMN corporate members from developing countries, 33 non-member companies and 58 representatives from international stakeholders from academia and global organizations attended. This year's discussions focused on equity and self-sufficiency for vaccine access and manufacturing, particularly in Africa.

In 2021, scientific and technological developments have enabled different efficacious vaccines to help tackle the COVID-19 pandemic. Nevertheless, the fight against the pandemic has been complicated by the emergence of different virus variants of concern, for which existing vaccines showed less effective.

Most importantly, inequitable distribution of the COVID-19 vaccines has left many countries defenseless against the pandemic, mostly in Africa. Despite efforts to supply the vaccines everywhere, Latin America had, in average, only 35% of the population vaccinated, and Africa less than 5% by end 2021. It was also recognized that around 50% of the COVID-19 vaccines that have been deployed through COVAX, were supplied from DCVMN manufacturers. Africa, a region of 1.2 billion people, has imported 99% of its vaccines so far. Thus, the establishment of vaccine manufacturing hubs in Africa is of great relevance in the fight against the COVID19 pandemic and also in the control of vaccine preventable diseases. The African stakeholders, supported by the broader global health community, aim to manufacture about 60% of locally administered vaccines, in the next 25 years.

Financial Statements

BALANCE SHEET AS AT 31 DECEMBER 2021

		31.12.2021		31.12.2020	
		CHF	USD	CHF	USD
ASSETS					
Current assets					
Liquidities		3'081'020.14	3'381'648.69	3'516'435.79	3'978'318.58
Advance deposit for expenses		4'555.50	5'000.00	4'419.50	5'000.00
Regus deposit		58.00	63.66	58.00	65.62
Prepaid expenses		6'831.05	7'497.59	8'468.49	9'580.82
Total current assets		**3'092'464.69**	**3'394'209.94**	**3'529'381.78**	**3'992'965.02**
TOTAL ASSETS		**3'092'464.69**	**3'394'209.94**	**3'529'381.78**	**3'992'965.02**
LIABILITIES					
Short-term liabilities	Notes				
Payables		11'935.84	13'100.49	0.00	0.00
Donations carryover	3.1	452'733.81	496'909.02	909'262.85	1'028'694.25
Accrued expenses		45'159.75	49'566.18	121'980.89	138'003.04
Total short-term liabilities		**509'829.40**	**559'575.69**	**1'031'243.74**	**1'166'697.29**
Unrestricted reserves					
Capital		2'498'138.04	2'815'806.88	2'292'627.03	2'362'205.63
Translation adjustment USD/CHF			5'546.31		10'460.85
Net result for the year		84'497.25	13'281.06	205'511.01	453'601.25
Total unrestricted reserves		**2'582'635.29**	**2'834'634.25**	**2'498'138.04**	**2'826'267.73**
TOTAL LIABILITIES AND RESERVES		**3'092'464.69**	**3'394'209.94**	**3'529'381.78**	**3'992'965.02**

INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2021

		2021		2020	
		CHF	USD	CHF	USD
Income	Notes				
Members contributions		498'039.60	549'000.00	509'425.50	519'000.00
Reversal provision for loss on members contributions for previous year		0.00	0.00	37'767.60	39'000.00
Loss on members contributions		0.00	0.00	-37'767.60	-39'000.00
Donations received		258'519.64	284'487.97	1'076'092.66	1'148'884.15
Carryover from previous year		909'262.85	1'028'694.25	448'605.49	463'244.00
Donations carryover to the next year	3.1	-452'733.81	-496'909.02	-909'262.85	-1'028'694.25
Reimbursement of donations	3.2	-62'141.79	-66'876.66	0.00	0.00
Annual meeting contribution participants		1'074.92	1'150.00	1'800.82	1'890.00
Total income before financial income		**1'152'021.41**	**1'299'546.54**	**1'126'661.62**	**1'104'323.90**
Total income		**1'152'021.41**	**1'299'546.54**	**1'126'661.62**	**1'104'323.90**
Operating expenses					
Best practice supply WG		-73'280.43	-79'375.38	-27'904.80	-30'000.00
Training Initiative		-116'805.10	-128'000.49	-93'244.94	-98'274.68
Regulatory Forum initiative		-169'822.88	-184'733.41	-122'747.84	-131'356.05
Knowledge exchange and databases initiative		-43'399.93	-46'803.54	-15'839.88	-17'004.75
Pharmacovigilance initiative		-28'662.16	-30'867.05	-13'173.88	-13'750.00
Annual General Meeting		-19'785.31	-20'911.25	-73'336.60	-80'008.30
Total operating expenses		**-451'755.81**	**-490'691.12**	**-346'247.94**	**-370'393.78**
Staff Costs					
Salaries		-485'399.88	-527'146.62	-253'610.50	-264'700.15
Social contributions AVS/AI/APG/AC/PCFam		-27'416.25	-29'529.93	-23'341.70	-24'837.93
Social and accident insurances		-5'630.35	-6'298.67	-5'144.60	-5'575.36
LPP contribution		-18'482.60	-20'213.85	-17'129.25	-18'107.82
Total staff costs		**-536'929.08**	**-583'189.07**	**-299'226.05**	**-313'221.26**
Other operating expenses	Notes				
Office rental		-7'340.81	-8'028.10	-7'427.06	-7'719.59
Office insurance		-350.25	-387.79	-389.15	-401.85
Office supplies		-13'283.59	-14'368.27	-2'567.43	-2'743.39
Accounting services		-26'033.05	-27'808.00	-14'894.90	-16'375.63
Legal consulting	3.3	-18'048.35	-18'556.80	-70'813.75	-79'976.93
HR and payroll services		-2'587.50	-2'838.55	-28'171.10	-30'932.47
Technical support by FVMR Hub		-37'466.45	-41'304.36	-23'626.33	-25'000.00
Other services		-46'165.00	-50'000.00	0.00	0.00
Financial audit		-11'161.55	-11'656.95	-10'770.00	-12'760.82
Publications		-2'154.00	-2'366.36	-7'838.26	-8'143.48
Management expenses		-2'762.55	-3'001.53	-1'322.95	-1'401.73
Miscellaneous		-1'028.20	-1'102.19	-1'058.57	-1'103.50
Total other operating expenses		**-168'381.30**	**-181'418.90**	**-168'879.50**	**-186'559.39**
Earnings before interest and taxes		**-5'044.78**	**44'247.45**	**312'308.13**	**234'149.47**
Financial expenses					
Interests paid		-88.62	-97.25	0.00	0.00
Bank and PayPal charges		-3'188.96	-3'478.69	-1'692.80	-1'775.26
Foreign exchange loss		108'718.26	-10'598.02	-333'225.29	-12'536.81
Total financial expenses		**105'440.68**	**-14'173.96**	**-334'918.09**	**-14'312.07**
Earnings before taxes		**100'395.90**	**30'073.49**	**-22'609.96**	**219'837.40**
Prior-period and extraordinary income and expenses					
Extraordinary income		0.00	0.00	244'987.77	252'982.00
Others income		1'237.00	1'355.91	822.00	849.17
Taxes on previous year		885.30	1'359.98	60.40	-1'002.00
Total pior-period income and expenses		**2'122.30**	**2'715.89**	**245'870.17**	**252'829.17**
Result before taxes		**102'518.20**	**32'789.38**	**223'260.21**	**472'666.57**
Local taxes		-18'020.95	-19'508.32	-17'749.20	-19'065.32
Net result for the year		**84'497.25**	**13'281.06**	**205'511.01**	**453'601.25**

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

BALANCE SHEET AS AT 31 DECEMBER

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FERNANDO
LOBO
TREASURER
10-JUN-2022

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER

	Notes	2021 CHF	2021 USD	2020 CHF	2020 USD
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Loss on members contributions		0.00	0.00	-37'767.60	-39'000.00
Donations received		258'519.64	284'487.97	1'076'092.66	1'148'884.15
Carryover from previous year		909'262.85	1'028'694.25	448'605.49	463'244.00
Donations carryover to the next year	3.1	-452'733.81	-496'909.02	-909'262.85	-1'028'694.25
Reimbursement of donations	3.2	-62'141.79	-66'876.66	0.00	0.00
Annual meeting contribution participants		1'074.92	1'150.00	1'800.82	1'890.00
Total income before financial income		1'152'021.41	1'299'546.54	1'126'661.62	1'104'323.90
Total income		1'152'021.41	1'299'546.54	1'126'661.62	1'104'323.90
Operating expenses					
Best practice supply WG		-73'280.43	-79'375.38	-27'904.80	-30'000.00
Training Initiative		-116'805.10	-128'000.49	-93'244.94	-98'274.68
Regulatory Forum initiative		-169'822.88	-184'733.41	-122'747.84	-131'356.05
Knowledge exchange and databases initiative		-43'399.93	-46'803.54	-15'839.88	-17'004.75
Pharmacovigilance initiative		-28'662.16	-30'867.05	-13'173.88	-13'750.00
Annual General Meeting		-19'785.31	-20'911.25	-73'336.60	-80'008.30
Total operating expenses		-451'755.81	-490'691.12	-346'247.94	-370'393.78
Staff costs					
Salaries		-485'399.88	-527'146.62	-253'610.50	-264'700.15
Social contributions AVS/AI/APG/AC/PCFam		-27'416.25	-29'529.93	-23'341.70	-24'837.93
Social and accident insurances		-5'630.35	-6'298.67	-5'144.60	-5'575.36
LPP contribution		-18'482.60	-20'213.85	-17'129.25	-18'107.82
Total staff costs		-536'929.08	-583'189.07	-299'226.05	-313'221.26
Other operating expenses					
Office rental		-7'340.81	-8'028.10	-7'427.06	-7'719.59
Office insurance		-350.25	-387.79	-389.15	-401.85
Office supplies		-13'283.59	-14'368.27	-2'567.43	-2'743.39
Accounting services		-26'033.05	-27'808.00	-14'894.90	-16'375.63
Legal consulting	3.3	-18'048.35	-18'556.80	-70'813.75	-79'976.93
HR and payroll services		-2'587.50	-2'838.55	-28'171.10	-30'932.47
Technical support by FVMR Hub		-37'466.45	-41'304.36	-23'626.33	-25'000.00
Other services		-46'165.00	-50'000.00	0.00	0.00
Financial audit		-11'161.55	-11'656.95	-10'770.00	-12'760.82
Publications		-2'154.00	-2'366.36	-7'838.26	-8'143.48
Management expenses		-2'762.55	-3'001.53	-1'322.95	-1'401.73
Miscellaneous		-1'028.20	-1'102.19	-1'058.57	-1'103.50
Total other operating expenses		-168'381.30	-181'418.90	-168'879.50	-186'559.39
EARNINGS BEFORE INTEREST AND TAXES		-5'044.78	44'247.45	312'308.13	234'149.47
Financial expenses					
Interests paid		-88.62	-97.25	0.00	0.00
Bank and PayPal charges		-3'188.96	-3'478.69	-1'692.80	-1'775.26
Foreign exchange loss		108'718.26	-10'598.02	-333'225.29	-12'536.81
Total financial expenses		105'440.68	-14'173.96	-334'918.09	-14'312.07
EARNINGS BEFORE TAXES		100'395.90	30'073.49	-22'609.96	219'837.40
Prior-period and extraordinary income and expenses					
Extraordinary income		0.00	0.00	244'987.77	252'982.00
Others income		1'237.00	1'355.91	822.00	849.17
Taxes on previous year		885.30	1'359.98	60.40	-1'002.00
Total pior-period income and expenses		2'122.30	2'715.89	245'870.17	252'829.17
RESULT BEFORE TAXES		102'518.20	32'789.38	223'260.21	472'666.57
Local taxes		-18'020.95	-19'508.32	-17'749.20	-19'065.32
NET RESULT FOR THE YEAR		84'497.25	13'281.06	205'511.01	453'601.25

FERNANDO LOZOS
TREASURER
10-JUN-20

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.

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 2021 the liability to the pension scheme amounted to CHF 9'635.40/ USD 10'575.57 (31 December 2020: CHF 4'234.45 / USD 4'790.64).

Explanations of income and expenses statement

3.1 ***Donations carryover to the next year***

The amount of CHF 452'733.81 / USD 496'909.02 (PATH for USD 365'630.73 and PSPT for USD 131'278.29) was unused by 31st December 2021 and therefore deferred as carryover to be disbursed in 2022, 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 ***Reimbursement of donations***

CHF 62'141.79 / USD 66'876.66 (corresponding to GBP 48'438.53) were reimbursed upon request of the donor, due to impossibility to implement activities within the agreed timeframe, due to COVID pandemic.

3.3 *Legal consulting*

In 2021 DCVMN engaged an external legal services firm to validate the approval of the new statutes and bylaws for the association.

3.4 *Travel expenses*

In 2021 due to the pandemic and international health security regulations all travel was cancelled.

4. General comments

1. DCVMN annual revenue from memberships, donations and financial gains in 2021 decreased by 56%, to CHF 695'492.37 (USD 767'761.31) before carryover, and before the variation on the provision on members contributions, from CHF 1'587'318.98 (USD 1'669'774.15), in 2020. This is mainly related to decrease partnerships and donations, as compared to 2020.

2. Membership status as of December 2021 indicated that there were 42 members, of which 15 were full members (with WHO PQed vaccines). In 2021 one member left the network while two new members joined; all the remaining members settled their membership contributions.

3. The Network's activities and interim financial statements (up to Q3/2021) were presented by the Treasurer, on behalf of the Executive Committee, to the General Assembly of members on 20th October 2021, at a virtual meeting, due to COVID-19 pandemic.

4. The Board of members proposed budget for 2022 approved by the members assembly is targeted at USD 1'932'000.- income and ca. USD 2'040'250.- for expenses, which includes carryover funds from donors.

5. The income budget for 2022, was based on the assumptions below :

a) a pledge of USD 500'000.- (PATH), allocated for training and related activities in 2022.

b) the membership contributions expected to remain similar to 2021, estimated at slightly over USD 550'000.-. 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. 200'000.-USD, for workshops and AGM.

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

6. The approved budget for 2022 will have an approved carryover amount of CHF 119'607.65 / USD 131'278.29 (NIIMBL) and CHF 333'126.16 / USD 365'630.73 (PATH) corresponding to activities funded by respective donors.

7. 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.

8. Of note, in 2021 the USD/CHF exchange rate contributed to foreign exchange gain of CHF 108'718.26 / USD -10'598.02, that reflected the value of the dollar on 31 December 2021, 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.

The unaudited financialstatements were preparedby Multifiduciaire Genève S.A., (www.multigeneve.ch), under the oversight and responsibility of DCVMN Board of members.

ANNEX

1. DCVMN Board Structure 2020-23

The DCVMN Board[23] 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 11 formal governance meetings, on virtual platform, on the following dates: 20th January, 23rd February, 24th March, 4th May, 01st June, 06th July, 03rd August, 07th September, 05th October, 12th November, 13th December, 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://www.dcvmn.org/Meeting-minutes*. In addition, the Board had a confidential meeting with CEO on March 4th to set direction for the organization to take total number of meetings to 12.

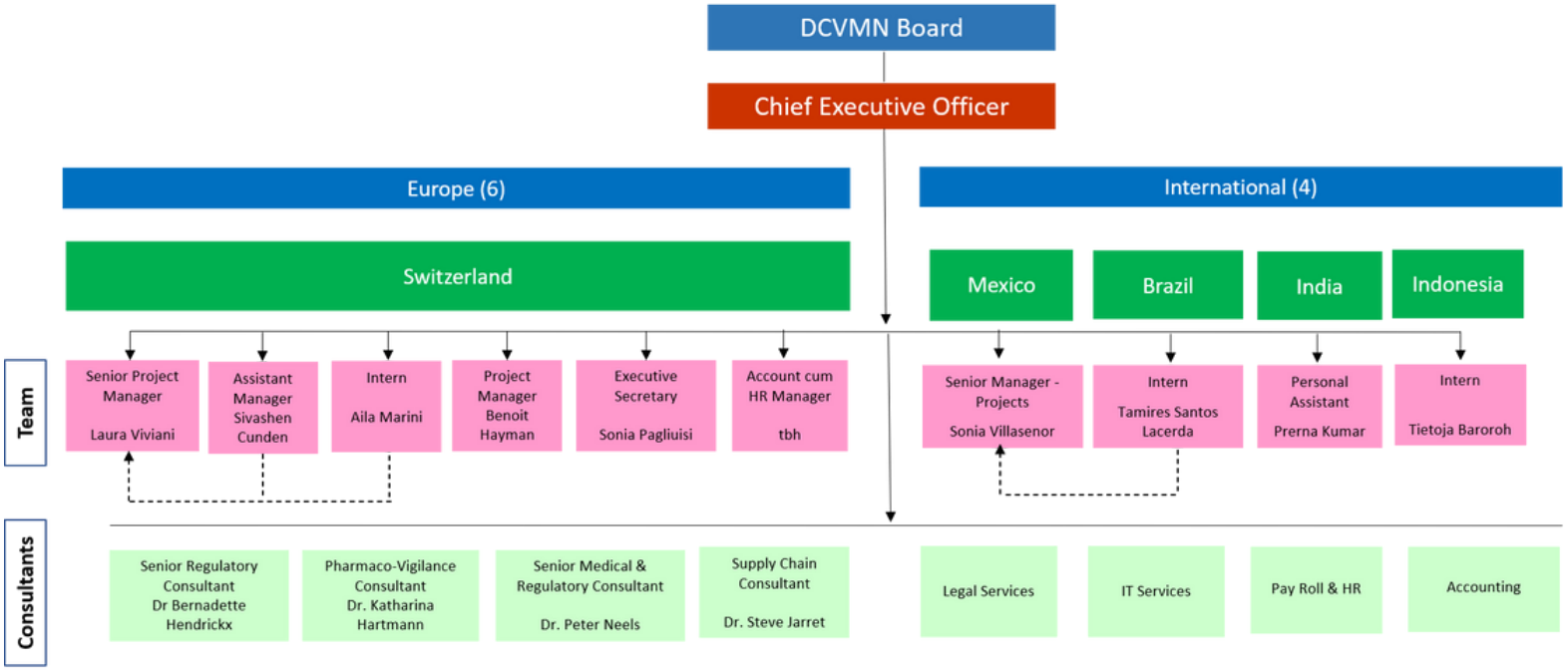
Role	Name	Affiliation	Attendance out of 12 virtual meetings in 2021
Chair	Mr. Sai D. Prasad	Bharat Biotech	9
Co-chair	Mr. Patrick Tippoo	Biovac	11
Treasurer	Mr. Fernando Lobos	Sinergium	11
Member	Ms. Lingjiang Yang	CNBG of Sinopharm	12
Member	Mr. Adriansjah Azhari	BioFarma	11
Member	Mr. Tiago Rocca	Butantan	10
Member	Ms. Wendy Huang	Innovax	9
CEO (non-voting)	Mr. Rajinder Kumar Suri	DCVMN International	12
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	10

[23] https://www.dcvmn.org/DCVMN-Board

2. Donors Advisory Committee

The Donors Advisory Committee[24] (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 FVMRH/Imperial College London, 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 2021 (01st March, 01st June, 01st September, 10th December).

3. DCVMN Secretariat Structure 2022



Secretariat Organogram 2022

[24] https://www.dcvmn.org/Donors-Advisory-Committee

4. Membership to Boards/High Level Committees

GAVI BOARD

Mahima Datla
Shu Xiang

PCC

Sai D Prasad

ACT-A

Sai D Prasad
Rajinder Suri

CCM

Mahima Datla

COVAX MANUFACTURING LEADERSHIP TEAM

Sai D Prasad
Rajinder Suri

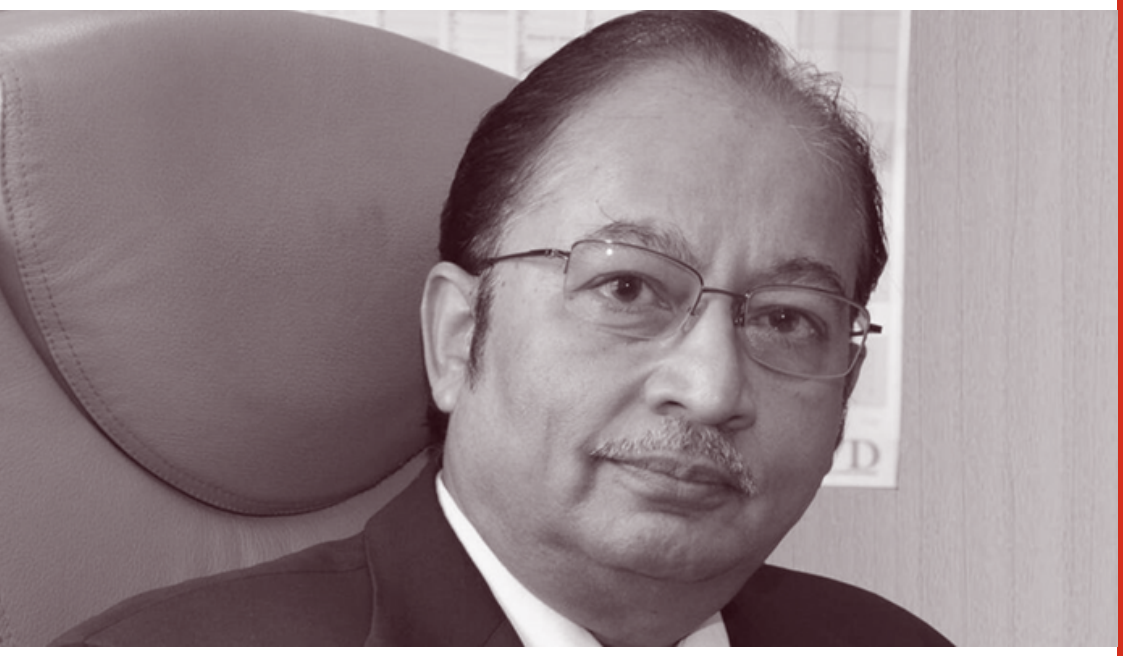
5. Membership at Expert Groups

Acknowledgements

We are grateful to 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 for a grant to DCVMN (grant no. OPP1204376), NIIMBL, and PATH for supporting the professional training programs, and PATH for supporting the Annual General Meeting 2020, as well. Some activities reported herein were also partly funded the Engineering and Physical Sciences Research Council (EPSRC, grant number: EP/R013764/1).

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.



LATE TO DR. SS JADHAV (1949-2021)

December 7th, 2021 was a sad day for the vaccine industry with the passing away of Dr. Suresh Jadhav: a humble, friendly yet very knowledgeable and highly respected person. His warm smile and kind words are still on our minds.

This is to pay a tribute to his exemplary lifetime and dedication to vaccines and immunization.

He was a great vaccinologist and one of the pillars with a pivotal role, for over 40 years in building the Serum Institute of India global outreach, in getting WHO pre-qualification of several products.

Dr. Jadhav was also instrumental in leading the Developing Countries Vaccine Manufacturers Network into its current status and we owe him a huge debt of gratitude.

We shall continue our work in respect of his life, legacy and memory!

dcvmn

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