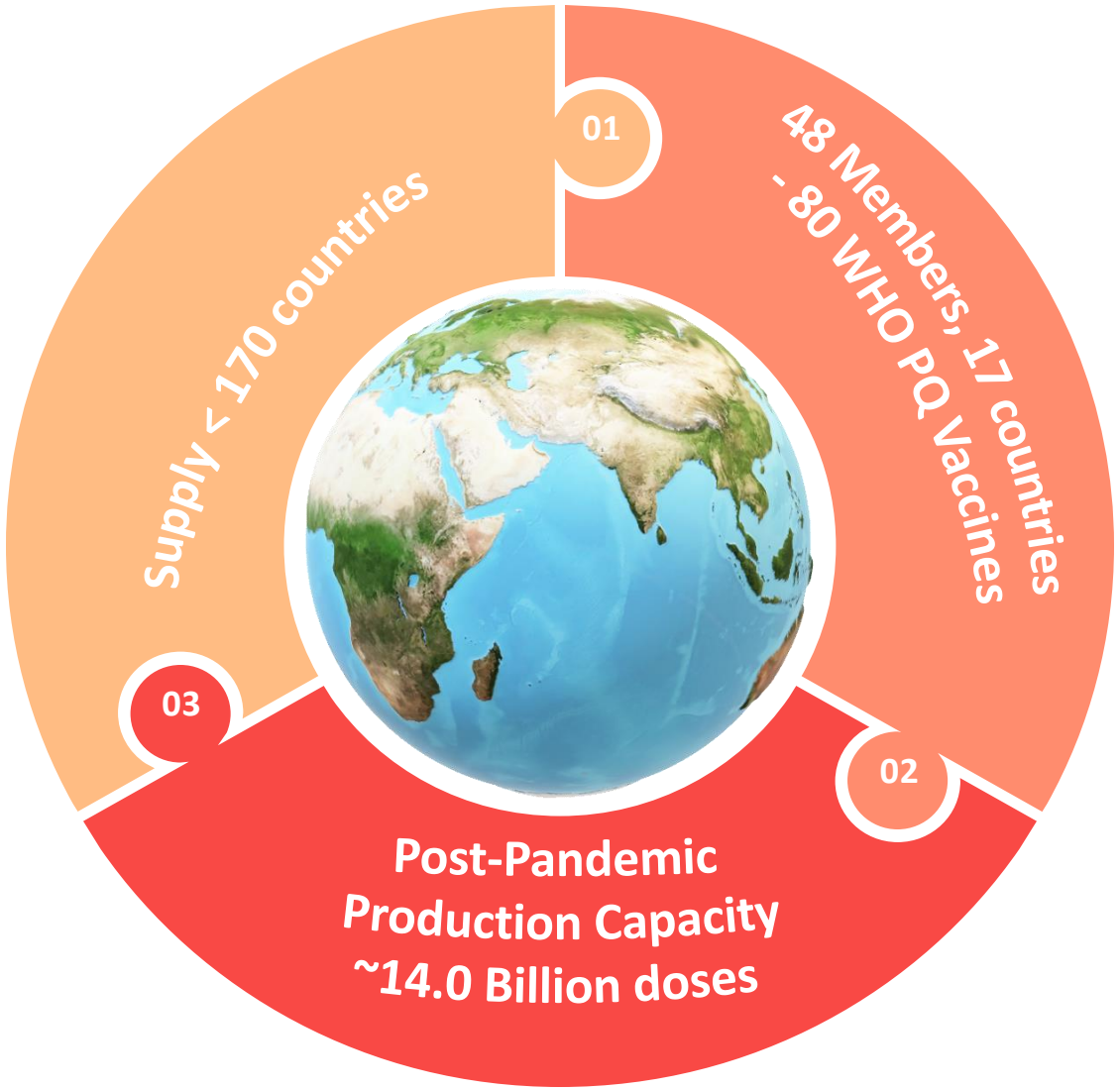
25th DCVMN Annual General Meeting 2024, São Paulo, Brazil October 16th – 18th, 2024

– An Update

Rajinder Suri
CEO-DCVMN International

PDVAC, Geneva | 9th December, 2024,

DCVMN
Developing Countries Vaccine Manufacturers Network



48 manufacturers engaged in Vaccine Innovation, R&D, Production and Delivery!

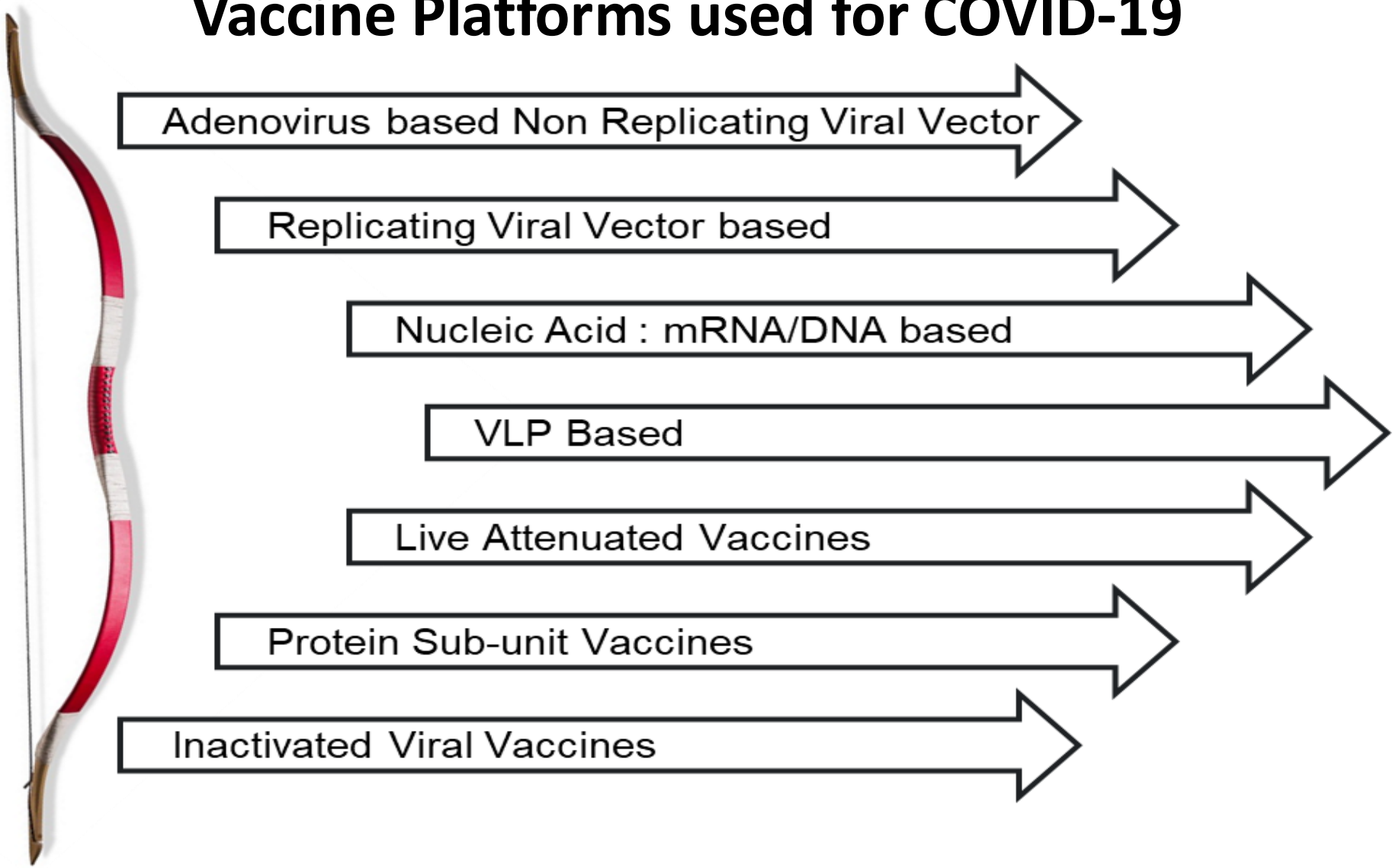
DCVMN International represents **17** countries present in all WHO Regions with **80** prequalified vaccines

DCVMs supply vaccines to over **170** countries globally

Protecting people from global diseases since 2000.

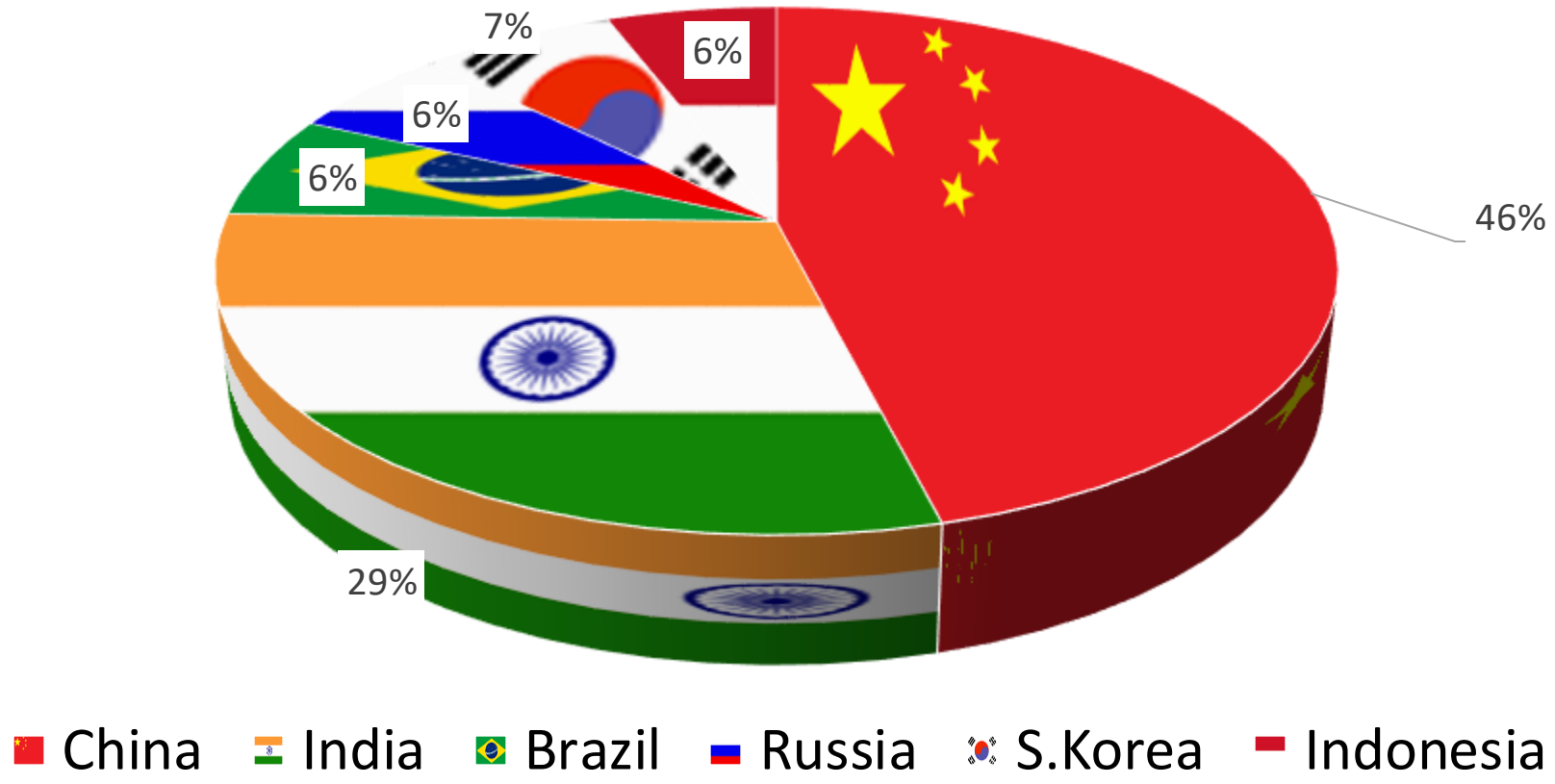
DCVMN
Developing Countries Vaccine Manufacturers Network

Vaccine Platforms used for COVID-19



COVID19 Vaccines: DCVM's Contribution

>8.0 Billion Doses!



Source: Internal Estimates

25th DCVMN Annual General Meeting 2024, São Paulo, Brazil
October 16th – 18th, 2024 – An Update

Silver Jubilee Celebration!

Launch of a video commemorating **25 years** of progress with reflections from leadership of global health agencies and DCVMN on **DCVMs impact in vaccine innovation, development, production, delivery and equity!**

Theme

"Steering Change to Augment Vaccine Access & Environmental Sustainability"

Showcasing DCVMN's commitment to safe, affordable, equitable vaccines

Attendees

Global leaders in Vaccine Policy Making, International Organizations like WHO, GAVI, CEPI, Africa CDC, UNICEF, PAHO, BMGF, PATH, IFC, DFC, FIND, IFPMA, Regulators, Academia, Researchers, Scientists and stalwarts from Public and Private sector organizations from Developing Countries.

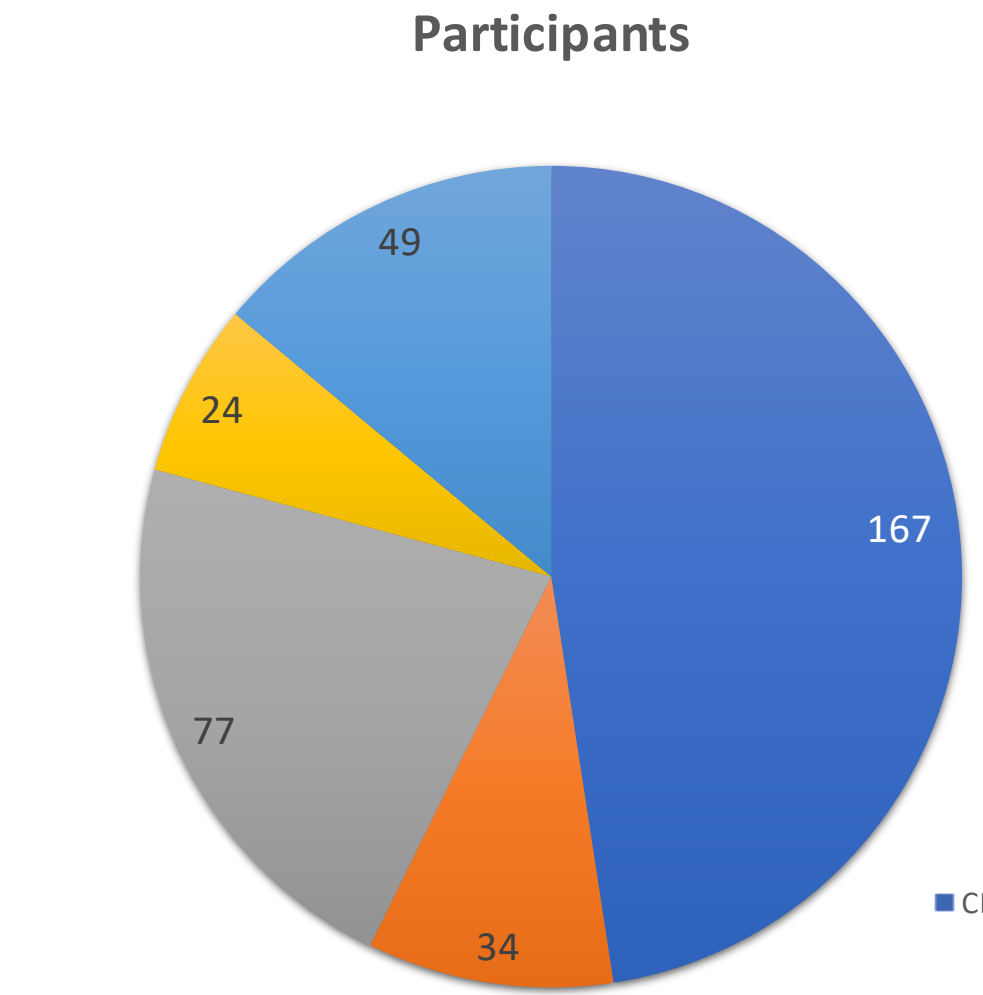
25th DCVMN AGM, brought together

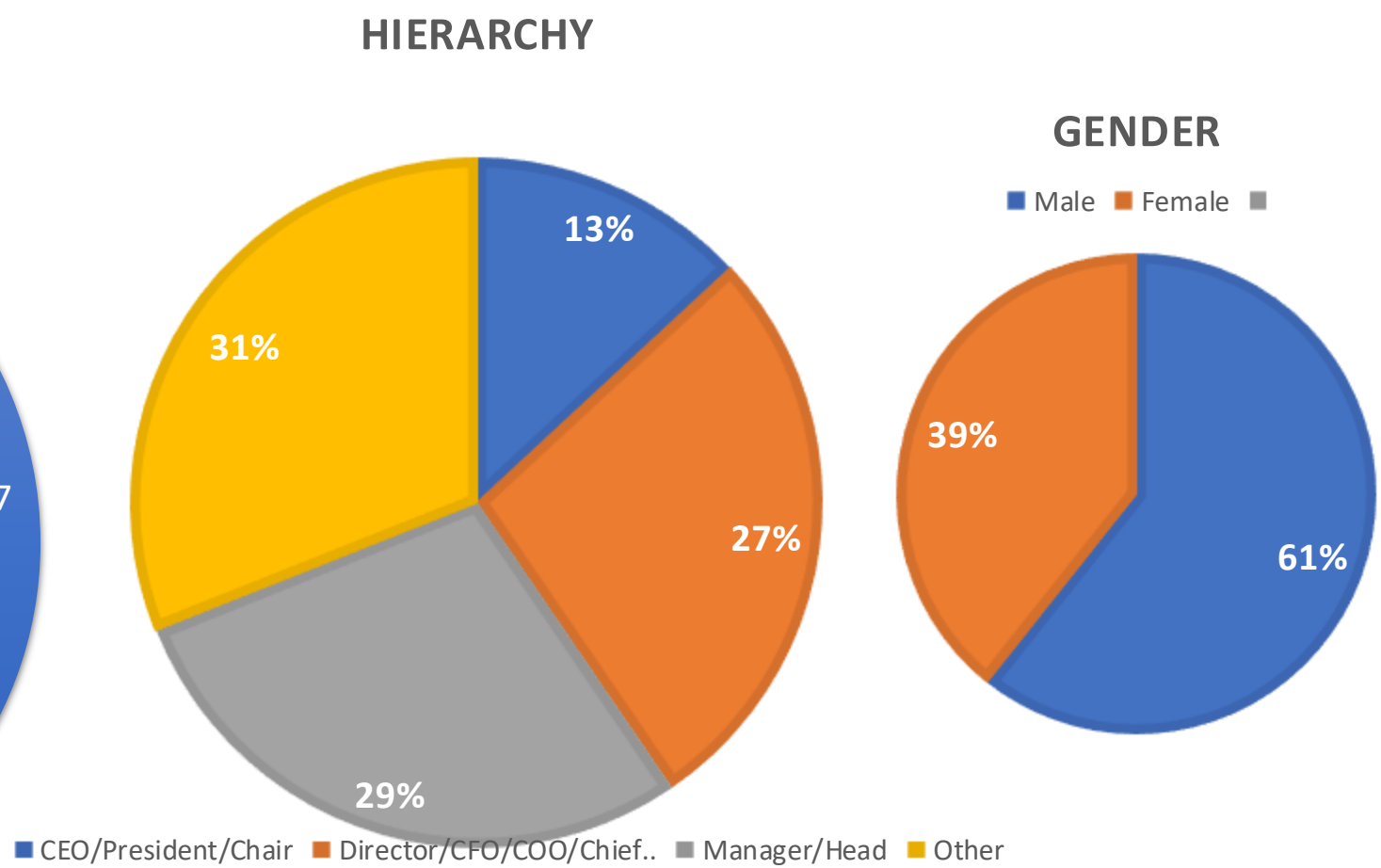
363
Participants

140
High-level speakers

29
Intense sessions

25th DCVMN AGM-Participation





Key Challenges Addressed:

1. Global Pandemic Prevention, Preparedness & Response and Equitable Access to LICs
2. Regulatory Harmonization and Clinical Development leading to Timely Access of Vaccines in LICs & LMICs
3. Priority Vaccines: Polio, TB, Dengue, Malaria and Meningitis
4. Private Sector Engagement to Boost Regional Manufacturing
5. Digital Technology and Impact of AI on Vaccine Manufacturing and Supply Chain
6. Impact of Climate Change, Environment Sustainability & Net-Zero
7. Innovate: International Network for Vaccine Safety Surveillance Study
8. Building Capacity: Vaccine Workforce Development Program
9. Collaborating to Augment Vaccine Supply Chain Security
10. Biodefence Strategies: An insurance against Biothreats
11. Counter Vaccine Hesitancy and Build Confidence
12. Partnerships Ecosystem: Gaps, Resources and Capabilities

Key messages emerged from 25th DCVMN AGM: Collaboration

1. With a focus on LMICs, strengthening equity in vaccine access with support from Global Partners like WHO, GAVI, CEPI,UNICEF, BMGF and commitments on investment in vaccines to support regional health challenges for climate-related and emerging diseases ensuring equitable access!

2. Need to develop novel financial tools tailored for vaccine manufacturers in LMICs, public-private partnerships and flexible financing options to support capacity and accessibility in underserved regions and promoting regional manufacturing hubs.

Key messages emerged from 25th DCVMN AGM
Regulatory Harmonization

1. Streamlined review processes across LMICs like in COVID-19, which allows faster global regulatory coordination and vaccine approvals.
2. Collaborations between WHO and NRAs to streamline approval and scale-up capacity.
3. Adoption of frameworks like WHO's Maturity Level 3 and 4 to ensure consistent standards and rapid approvals. Continued advocacy for standardized regulatory practices.

Key messages emerged from 25th DCVMN AGM
Climate Change, Environmental & Social Responsibility

1. **Net-Zero Goals:** Reducing the carbon footprint in vaccine supply chains and manufacturing processes.
2. **UNICEF and PAHO Insights:**
   - Strategies for sustainable procurement and logistics.
   - Efforts to cut emissions by using eco-friendly shipping and reduced packaging.
3. **Innovations in Energy Efficiency:** Promotion of renewable energy sources like solar and wind in manufacturing.
4. **Green Vaccine Manufacturing**: Plans to reduce carbon footprint and improve sustainability in manufacturing.
5. **Global Health Commitment**: Commitment to integrating health equity with environmental stewardship in vaccine production.

Key messages emerged from 25th DCVMN AGM
Workforce Development for Vaccine Manufacturing

1. **Training and Capacity Building Programs**
   - Emphasis on developing technical skills and leadership within the vaccine manufacturing workforce.
2. **Global and Regional Efforts**
   - Support from the Gates Foundation, Africa CDC, and NIIMBL in skill development for sustainable vaccine production.
3. **Future-Ready Workforce**
   - Preparing for emerging technologies and sustainable practices in vaccine production.

25th DCVMN AGM – Collaboration with WHO:

- **Inaugural Session** featuring **11** speakers, including global leaders like DG WHO, CEO-GAVI, Emma Wheatley standing in for CEO-CEPI, Director-UNICEF, Director-PAHO and vaccine experts from around the globe
- **Special sessions with WHO**
  1. f2f Session with Dr. Bruce Aylward and DCVMN Member companies
  2. mRNA Tech-Transfer Program by WHO/MPP
- **Key note sessions were Chaired/addressed by**
  - Dr. Bruce Aylward, ADG
  - Dr. Yukiko Nakatani, ADG
  - Dr Rogerio Director-RPQ
  - Dr Birgitte, Dr Jicui Dong
  - Ms Tara Prasad

WHO’s Interaction with Industry

WHO’s perspective shared with DCVMN

1. **Focus on Equity:** Prioritizing zero-dose children (14.5 million globally) to advance the equity agenda.
2. **Global Strategy 2025-2028:** Anchored in six objectives, including immunization as a cornerstone of primary healthcare and climate resilience.
3. **Scaling Key Vaccines:** Emphasis on underutilized vaccines like HPV, Malaria, TB, and dengue.
4. **Regulatory and PQ Efficiency:** Commitment to improving PQ transparency, data quality and reducing approval timelines.
5. **Market Insights and Surveillance**: Strengthening disease burden data, demand forecasting and proactive emergency response plans.

WHO’s Interaction with Industry

WHO’s Expectations from DCVMN

1. **Providing Affordable Vaccine Access**: Ensuring vaccines are accessible and affordable in LMICs by scaling production and capacity.
2. **Innovative R&D**: Investing in TB, dengue, and chikungunya vaccines to address unmet health needs.
3. **Collaborative Efforts**: Supporting South-South partnerships to expand regional manufacturing capacity.
4. **Alignment with WHO**: Full solidarity on Immunization Agenda 2030 goals, prioritizing universal immunization coverage.
5. **Advocacy for Streamlined PQ**: Advocating for strengthened resources and clearer processes in WHO PQ to accelerate access.

WHO’s Interaction with Industry

DCVMN’s perspective shared with WHO

1. **Pre-Qualification (PQ) Processes:**
   - Increase efficiency and capacity of the WHO PQ team to expedite approvals.
   - Provide upfront guidance for data submission and consultation processes to avoid delays.
   - Develop a priority list for urgent vaccines to streamline PQ pathways.
2. **Strengthening Regulatory Harmonization**
   - Broader adoption and strengthening of the Collaborative Registration Procedure (CRP).
   - Advocacy for consistent global regulatory standards to avoid duplication and delays.
3. **Improved Demand Forecasting and Market Transparency**
   - Collaborate with GAVI and UNICEF to provide more reliable demand forecasts.
   - Expand country-by-country and regional assessments to understand vaccine portfolio priorities.

WHO’s Interaction with Industry

DCVMN’s perspective shared with WHO

4. Support for Disease Surveillance and Data Collection

- To advocate for increased funding and integration of surveillance into GAVI 6.0 strategy.
- Develop tools for better data sharing and disease burden assessment, especially in LMICs.
- Support manufacturers in accessing and utilizing surveillance data to guide R&D efforts.

5. Clear Guidance on Vaccine Portfolio Optimization

- Provide clear, evidence-based recommendations on which vaccines to prioritize at national levels.
- Assist countries in rationalizing vaccine portfolios to balance resources and coverage.

6. Greater Collaboration and Transparency

- Regular consultations between WHO and DCVMN members to align on strategic priorities..
- Support South-South collaborations to expand manufacturing capacity in underserved regions.

Key messages emerged from 25th DCVMN AGM
Advice received from the collective wisdom of all stakeholders:

1. **Invest in yourself, position differently**
2. Work on public dynamics and to focus on speed, scale and access
3. **Bridging the gap between vaccines and vaccinations & a unified communication strategy**
4. **Vaccine Safety Surveillance: Underreporting and data gaps**: A critical challenge in vaccine safety surveillance is the underreporting and information gaps between manufacturers, national health systems, and patients. A global data-sharing mechanism, engaging with CEPI and DCVMN, is needed to address this issue, along with capacity-building efforts in LMICs for active vaccine safety surveillance.
5. **High capital costs**: Vaccine manufacturers face challenges due to high capital costs, debt burdens, and low margins. Innovative financing approaches, such as blended finance (a mix of public and private funding), were discussed as solutions with focus on getting access to right type of financing by bringing in different institutions together
6. Strengthening R & D Ecosystem
7. **Strengthening Global Vaccine Manufacturing**
8. **Pre-Pandemic Collaborations**

Key messages emerged from 25th DCVMN AGM
Advice received from the collective wisdom of all stakeholders:

9. Technology Transfer between DCVMs will be essential to make vaccines more affordable and accessible, particularly in the Global South.

10. Secure Demand forecast and demand certainty

11. Build new relationships

12. Cross regional, South-South and North-South Collaborations & Partnerships

13. Act faster than Governments, build more robust action plans

14. Take Big challenges and learn to manage risks

15. Environmental Sustainability due to climatic changes and resultant diseases, AI and Digital health are going to be the new key game changers

16. Bioeconomy market is going to swell from 4 trillion dollars to 30 trillion dollars, thereby offering huge opportunities to be leveraged in the bioeconomy, biosecurity and biosafety arenas.

Take home messages for strategic consideration and action plan for DCVMN

- Be conscious of Geo-political changes
- Intensify Advocacy, by becoming a strong voice, amongst policy makers to make big impact
- Prioritize an integrated manufacturing and resilient supply chain system including trace & track technology for an equitable access to LICs and LMICs
- Building workforce development: To attract young talent and provide novel training and education programs, building the next generation of leaders in the vaccine industry and Quality culture is the key for capacity building for long term.
- To be prepared with strategies for biodefence threats with pull & push mechanism and community engagement
- Embark upon creating awareness about positive aspects of vaccines and countering vaccine hesitancy
- Think beyond vaccines

DCVMN's Strategic vision to support Global Health Goals as emerged from AGM, 2024

To provide sustainable, safe and equitable vaccines access worldwide

✓ **Sustainability**	Support member companies to achieve measurable reductions in environmental impact.
✓ **Safety Surveillance Expansion**	Support implementing and optimizing the global safety network
✓ **Capacity & Competency Building**	Support in strengthening the vaccine workforce and foster innovation to meet global health needs.

Announcements

Keeping in view the urgent need to build vaccine manufacturing capacity in Africa and encourage introduction and adoption of novel technologies within DCVMN, the 25th General Assembly of the member companies has approved the addition of a new segment of:

1. **Provisional New members** who are either oncourse to be AVMA recipients or harnessing novel technology even if not yet licensed to commercialize a vaccine and can receive DCVMN support in the coming months and years:
    a. Atlantic Life Sciences, Ghana, Africa
    b. DEK Vaccines, Ghana, Africa
    c. Gennova Biopharmaceuticals Ltd, Pune India innovators of heat stable mRNA vaccine

2. **Prospective full members**
    a. GCBC (earlier Shantha Biotechnics Ltd), India
    b. Finlay Institute Cuba
    c. Centre for Genetic Engineering & Biotevtecnology, Cuba

3. **Destination for next AGM**

- **Bali, Indonesia**

You are cordially invited!

Target Pathogens

Focus is on the following pathogens to provide stockpile when required:

- Mpox
- H5N1
- Sudan Ebolavirus
- Nipah
- Lassa Fever
- Rift Valley Fever
- West Nile
- Yellow Fever etc.

Mpox: DCVMN initiatives

- **At least 6 Vaccine manufacturers in DCVMN constituency are actively involved:**

1. **Bharat Biotech** has already completed animal tox studies successfully using similar MVA strain that is present in the Bavarian Nordic vaccine, and currently working for clinical plan
2. **CNBG**-VIROGIN is the strategic partner of Virogin in vaccine development and Virogin Biotech (a Canada based Biotech company)has developed a mRNA based mpox vaccine. The results have been published in Nature Communications. Briefly, they designed and tested three mRNA vaccines encoding monkeypox virus (MPXV) proteins A35R and M1R, The antigens encoded by the mRNA is from MPXV strain Zaire79. The antigens encoded by the mRNA is from MPXV strain Zaire79. For in vivo protection, they used Western Reserve (WR, VR-1354) as everybody else. POC study results have shown a great promise for a GO for IND enabling.
3. **Bio-Manguinhos, Brazil** has now two ongoing initiatives. One is fully internal, based on mRNA technology, and other in partnership with CT-Vacinas, based on Modified Vaccinia Virus Ankara

Mpox: DCVMN initiatives

4. IMBCAMS, China:

- Institute of Medical Biology Chinese Academy of Medical Sciences, a state-owned institute for R&D and supply of vaccines for human infectious diseases with 66 years history. They have successfully developed and launched HAV vaccines, OPV, IPV, EV71 vaccines in the past with their own independent research platform and commercialized system. Their plan is to develop a Mpox vaccinia vaccine upon modified attenuated Guang 9 strain as basis, through gene editing.

5. Panacea Biotec , India

- THSTI and Panacea Biotec are collaborating on the development of a recombinant protein nanocage-based Mpox vaccine candidate. Vaccine design consists of Mpox antigens which are over 99% conserved across clades, and, have the ability to induce strong humoral, T-cell, and neutralizing antibody responses. This candidate has already been evaluated for preclinical immunogenicity, and efficacy studies against the orthologous vaccinia virus.

6. Serum Institute of India

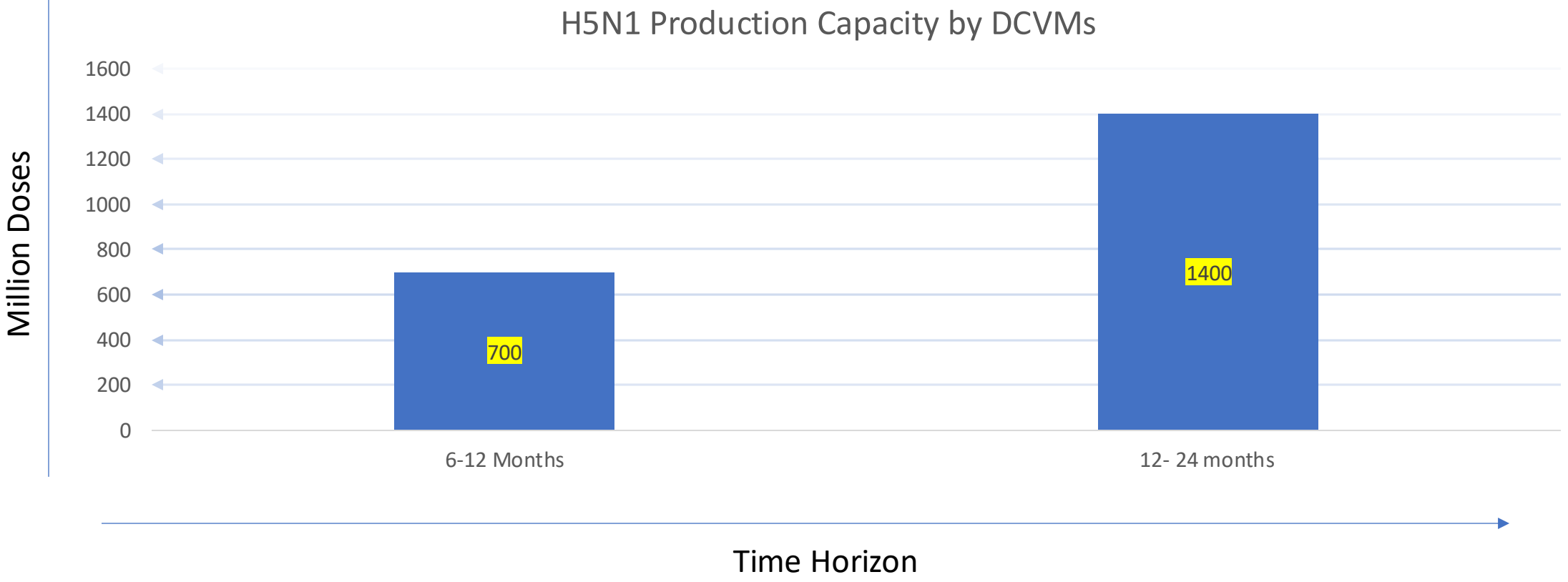
- SIIL is seriously working on Mpox program. Details can be shared when available.

H5N1 Vaccine: Work in Progress

To respond to the H5N1 challenge, DCMN members are toiling hard to come to speed and roll out vaccines

- ✓ Five of DCVMN members have already signed SMTAs with PIP Framework
- ✓ Commitment to donate a specified percentage of pandemic vaccine to PIP framework while ensuring another percentage to be supplied at affordable prices through UN agencies
- ✓ Time bound accelerated development
- ✓ A new project aiming to accelerate the development and accessibility of human avian influenza (H5N1) mRNA vaccine candidates for manufacturers in low- and middle-income countries has been launched on July 29, 2024. The Argentinian manufacturer Sinergium Biotech will lead this effort leveraging the WHO and the Medicines Patent Pool (MPP) mRNA Technology Transfer Programme. They have a total of 14 vaccine candidates for HA antigen under evaluation, for 3 different H5N1 avian influenza strains including the most prevalent clade.

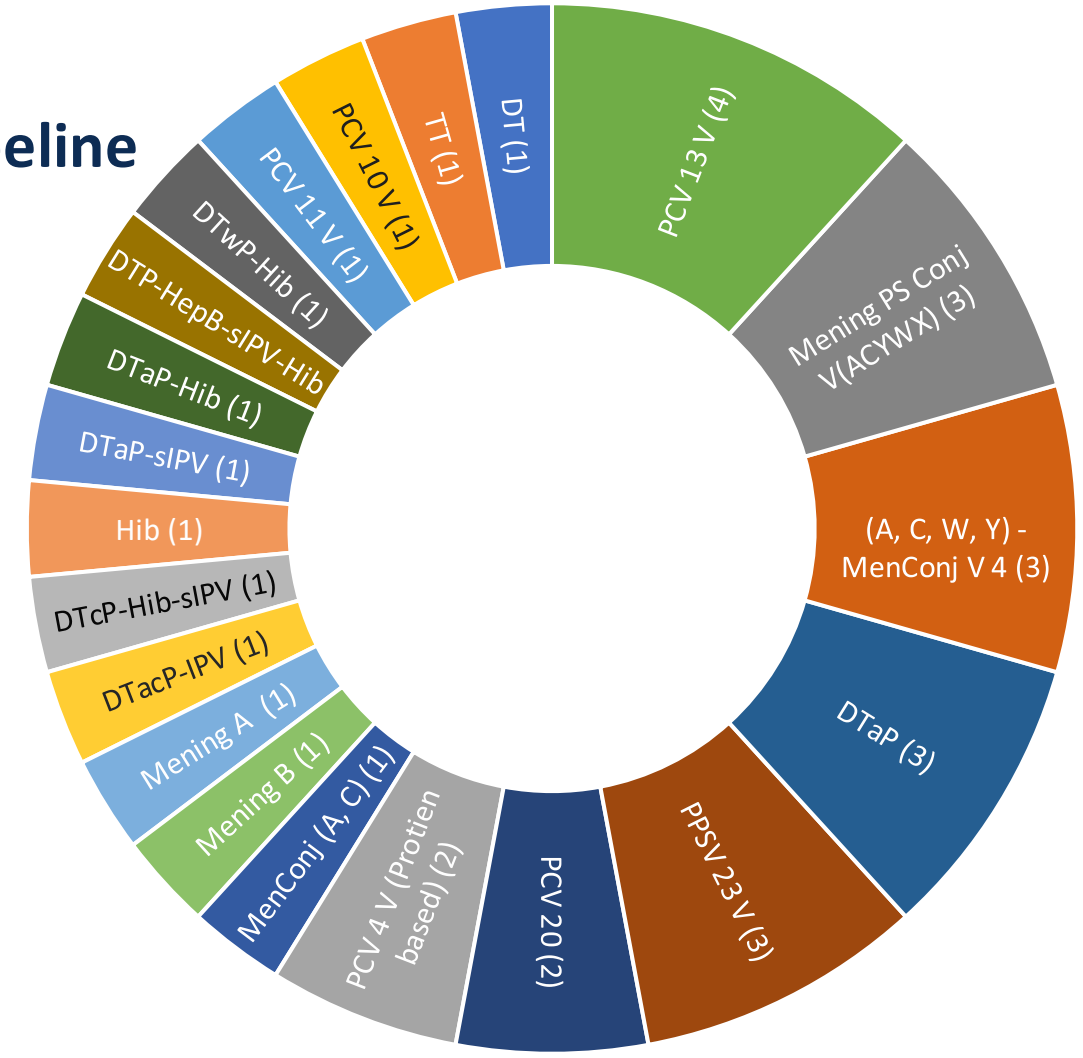
H5N1 Vaccine: Estimated Production Capacity



Approach

- While we at DCVMN endorse the Network of Network (NoN) Approach for scaling up vaccine production, however, we strongly recommend that this has to be sustainable proposition by ensuring:
    1. **Advance Market Commitments**
    2. **Firm Forecast**
    3. **Upfront Funding and**
    4. **Early access to novel technology, strains and clades**

DCVMN Spectrum of Innovative Bacterial Vaccine Pipeline



The Commitment

We at DCVMN remain committed to:

1. Innovation, R & D and Scaling up production
2. Capacity building and work force development in vaccine manufacturing in Africa, LATAM and other regions
3. Collaboration with stakeholders such as WHO, Africa CDC, PHAHM, Gavi, CEPI, PATH, BMGF, RVMC, Governments, Private & Public Research institutions!
4. To align with overarching outcome with WHO's Fourteenth General Program of Work, 2025-2028, specifically Outcomes 5.2: **'Preparedness, readiness, and resilience for health emergencies enhanced.' through 'The theory of change'!**

WHEN YOU THINK ABOUT VACCINES IN DEVELOPING COUNTRIES THINK OF DCVMN!

Protecting
people from
global diseases
since 2000.

DCVMN
Developing Countries Vaccine
Manufacturers Network