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Conference report

Vaccines: Shaping global health[☆]Sonia Pagliusi^{a,*}, Ching-Chia Ting^a, Fernando Lobos^b, the DCVMN Executive Committee Group¹^a DCVMN International, Route de Crassier 7, 1262 Nyon, Switzerland^b Sinergium Biotech, Ruta Panamericana, km 38.7, Garín, Buenos Aires P1619IEA, Argentina

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ABSTRACT

The Developing Countries Vaccine Manufacturers' Network (DCVMN) gathered leaders in immunization programs, vaccine manufacturing, representatives of the Argentinean Health Authorities and Pan American Health Organization, among other global health stakeholders, for its 17th Annual General Meeting in Buenos Aires, to reflect on how vaccines are shaping global health. Polio eradication and elimination of measles and rubella from the Americas is a result of successful collaboration, made possible by timely supply of affordable vaccines. After decades of intense competition for high-value markets, collaboration with developing countries has become critical, and involvement of multiple manufacturers as well as public- and private-sector investments are essential, for developing new vaccines against emerging infectious diseases. The recent Zika virus outbreak and the accelerated Ebola vaccine development exemplify the need for international partnerships to combat infectious diseases. A new player, Coalition for Epidemic Preparedness Innovations (CEPI) has made its entrance in the global health community, aiming to stimulate research preparedness against emerging infections. Face-to-face panel discussions facilitated the dialogue around challenges, such as risks of viability to vaccine development and regulatory convergence, to improve access to sustainable vaccine supply. It was discussed that joint efforts to optimizing regulatory pathways in developing countries, reducing registration time by up to 50%, are required. Outbreaks of emerging infections and the global Polio eradication and containment challenges are reminders of the importance of vaccines' access, and of the importance of new public-private partnerships.

1. Introduction

The Developing Countries Vaccine Manufacturers' Network (DCVMN) is the world's largest vaccine-industry alliance. In 2016, 50 corporate members are working to provide high-quality vaccines, and contribute to global health initiatives, ensuring uninterrupted vaccine supply to countries, to advance eradication of polio and facilitate response to emerging infectious diseases (EIDs) or outbreaks like the Zika outbreak [1].

[☆] IMPORTANT NOTE: This report summarizes the views of an international group of experts as presented at a scientific conference in a given time and context, and does not necessarily represent the decisions or the stated policy of any institution or corporation. Report of the Annual General Meeting of the Developing Countries Vaccine Manufacturers Network, 24–26 October 2016, Buenos Aires, Argentina.

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The 17th Annual General Meeting of the DCVMN was held, in Buenos Aires, Argentina, hosted by Sinergium Biotech. Nearly 200 professionals working in vaccine research, development, manufacturing and supply attended, including representatives from the global health organizations such as the Pan-American Health Organization (PAHO), Gavi: the vaccine alliance, World Health Organization (WHO), United Nations International Children's Fund (UNICEF), Biomedical Advanced Research and Development Authority (BARDA), Clinton Health Access Initiative (CHAI), International Vaccine Institute (IVI), Médecins Sans Frontières (MSF), PATH, Bill & Melinda Gates Foundation (BMGF), Institute for Translational Vaccinology (Intravacc), among other global health stakeholders, and representatives from 31 vaccine manufacturers from developing countries and 20 life sciences corporations.

M. Suhardono, DCVMN President, opened the meeting by thanking the Minister of Health of Argentina for attending, and Sinergium for hosting it. He provided a brief update on DCVMN: five new corporate members joined in 2016, including Amson Vaccines

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and Pharma from Pakistan, HLL Biotech, Green Signal Bio Pharma and Zydus Cadila from India, and Instituto Biologico Argentino (BIOL) from Argentina – the 50th member. He emphasized the importance of collaboration and partnerships among members for achieving sustainable supply of high-quality, affordable vaccines and to accomplish global health initiatives. One such initiative is the switch from trivalent (tOPV) to bivalent oral polio vaccine (bOPV) and eventually inactivated polio vaccine (IPV), in order to contain polioviruses better and, ultimately, eradicate polio.

J. Lemus, Minister of Health in Argentina, began with the reminder that vaccines and potable water are the most effective ways to reduce morbidity and mortality globally. The role of the Ministry of Health is to protect the Argentinian population and promote healthy living. The H1N1 outbreak in Argentina underscored the value of local vaccine manufacture. He also emphasized the importance of supporting international supply, and affirmed the Argentinian government's and vaccine manufacturers' commitment to work with PAHO to provide high-quality vaccines globally.

M-P. Kiemy reviewed evolving collaborative innovation in vaccine development. Historically, one scientist, like Edward Jenner, could develop a vaccine. Then came small groups, such as Louis Pasteur and colleagues. Innovation subsequently became the work of a large team, sometimes spanning several corporations. Now, after decades of intense competition for high-value markets, collaboration with developing countries has become critical, and involvement of multiple manufacturers as well as public- and private-sector investments are essential. The 10-year Meningitis A project and the 30-year malaria vaccine development illustrate the efforts for developing vaccines for African epidemics. The accelerated Ebola vaccine development in 2014 required urgent collaboration between manufacturers, regulatory authorities and funding agencies to respond to and contain the emerging outbreak [2]. Following the registration of the first dengue vaccine in 2015, the most advanced dengue vaccine, a collaboration between Butantan and National Institutes of Health (NIH) [3], encourages partnerships with DCVMs and public-sector entities. Full participation of DCVMN members in future innovative collaboration will require increased development capability, novel production processes and regulatory skills, along with equal partnerships, justified investments and national regulatory agencies (NRAs) capabilities. She concluded that commitment to public health as a joint responsibility is essential.

H. Sigman, Chairman of Group InSud and Sinergium welcomed meeting participants. He introduced Sinergium's technology transfer capabilities, providing an example of partnership between public and private sectors, and confirmed the importance of collaboration among vaccine manufacturers.

2. Access to vaccines

The Director of PAHO, C.F. Etienne, presented via video. PAHO has undertaken to make national health programs sustainable and affordable, encouraging improvements in quality and availability of vaccines from both private and public sectors. Rubella was eliminated from the WHO Americas region in 2015, and it is now the first region to be declared free of measles [4]. She thanked DCVMN members for their contribution to national immunization programs. PAHO is committed to continue collaboration with DCVMN members and welcome innovative suggestions, to ensure that the Americas have sustainable access to life-saving vaccines.

I. Danel, Deputy Director from PAHO, outlined achievements of public health goals in the Americas, including extension of the reach of national immunization programs, new vaccine introductions, strengthening of regulatory pathways and improving financing

and forecasting mechanisms. Elimination of measles from the Americas is a result of countries working together successfully. This was made possible by timely supply of measles-rubella (MR) and measles-mumps-rubella (MMR) vaccines by DCVMN members. In 2015, DCVM's vaccines represented 74% of the total volume of 250 million doses procured through PAHO's Revolving Fund. PAHO is constantly seeking alternative sources of vaccines and adopting strategies to enable manufacturers to find new opportunities. She encouraged DCVMN members to get involved in fast-track development of vaccines, to enhance sustainability of supply and to introduce required vaccines.

K. Owen from BMGF reviewed the number of deaths averted through immunization by 2015 [5], then discussed the challenge of creating stable vaccine supply in developing countries. Stable supply requires high-quality manufacturing capacity, committed financing, strong regulatory systems and predictable demand. BMGF's efforts have focused on partnering with manufacturers, stimulating procurement, and optimizing regulatory pathways in developing countries, to reduce registration time by up to 50%. Challenges around predictability remain. A recent example of challenge is the transition in demand from OPV to IPV. It is essential that DCVMs have strategies to sustain their business in a competitive market.

R. Bright presented BARDA's role in tackling emerging and re-emerging infectious diseases. The large number of potential EIDs and unpredictability of emergence requires multi-hazard strategies and investment in a broad spectrum of vaccine platforms. Emerging threats require a rapid and coordinated response which integrates diagnostics for early detection, therapeutics and vaccines. Collaboration between multiple groups to develop and evaluate vaccines and new supply and funding models are becoming increasingly necessary to respond efficiently. There are currently 38 companies developing Zika vaccine, including DCVMN members Bharat, Butantan, and Sinergium. He urged DCVMs who are working on Zika candidate vaccines to meet and foster possible partnerships.

F. Kristensen provided an overview about the new Coalition for Epidemic Preparedness Innovations (CEPI) [6]. CEPI aims to prioritize, stimulate, finance, coordinate and advance vaccine development against EIDs with epidemic potential, especially where market incentive alone will not achieve this. The Ebola response showed that it is possible to advance the clinical development of vaccines in an emergency. Manufacturing capability and capacity for vaccines is a bottle-neck during crises, thus the effort will focus on driving vaccine manufacturing pipelines, while also funding diagnostics and therapeutics. CEPI seeks multi-year donor contributions of up to one billion dollars between 2017 and 2021 from those aligned with the strategic objectives and mission. The operating principles are: equitable access, cost coverage and shared risks and benefits. Funding from CEPI will be available to vaccine producers or consortia with a track record of bringing vaccine candidates to human clinical trials. The founders of CEPI are the governments of India and Norway, the Bill and Melinda Gates Foundation, Wellcome Trust and The World Economic Forum (WEF). CEPI was, in fact, launched at the WEF Meeting in Davos, in January 2017.

J. Kalil discussed emerging and re-emerging diseases in tropical regions. Butantan is developing Dengue and Zika vaccines, currently in phase III clinical trials, and shows results comparable to the NIH vaccine [3]. Development of a Zika candidate vaccine was undertaken as an urgent response to the recent outbreak in South America. The ideal situation would have been to develop a combination vaccine against both Zika and Dengue. Butantan is willing to collaborate with other companies developing Zika vaccines to test candidate vaccines in an endemic area.

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