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Review

Delivering the promise of the Decade of Vaccines: Opportunities and challenges in the development of high quality new vaccines

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ABSTRACT

The Decade of Vaccines (DoV) initiative, launched in 2010, has as its mission "to extend, by 2020 and beyond, the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live".

Through their life-saving vaccines, the research-based vaccine companies represented by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Biotechnology Industry Organization (BIO) make a major contribution toward this vision. In this article, we begin by summarizing progress made over the past three decades in research and development (R&D) of new and future vaccines, and identify the opportunities and challenges faced by the research-based vaccine industry. We then review the Global Vaccine Action Plan (GVAP) [1] and provide IFPMA and BIO consensus perspectives on its six strategic objectives. Finally, we identify policy measures to support R&D of, and access to, high-quality, innovative vaccines.

Contents

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1. Background

The DoV was introduced at the World Economic Forum in Davos, Switzerland in January 2010, with a pledge by the Bill & Melinda Gates Foundation to dedicate $10 billion to the overall goal of researching, developing and delivering vaccines for the world's poorest countries. Drawing on a model developed by a consortium of the Institute of International Programs at the Johns Hopkins Bloomberg School of Public Health, the Foundation projected that over the next 10 years, by scaling up the delivery of life-saving vaccines in developing countries to 90% coverage, the international community could prevent the deaths of some 7.6 million children under 5 [2].

In December 2010, the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the National Institute of Allergy and Infectious Diseases (NIAID) and the Bill & Melinda Gates Foundation formally launched the DoV through a collaboration to create a GVAP, to "achieve key milestones in the discovery, development and delivery of life-saving vaccines to the most vulnerable populations in the poorest countries over the next decade" [3].

Following extensive consultations with DoV stakeholders – including IFPMA and BIO – a final draft of the GVAP was presented and endorsed at the 65th World Health Assembly in May 2012.

2. The contribution of the research-based vaccine industry

IFPMA and BIO believe that sustained access to and use of high quality and innovative vaccines are required for making the DoV a reality – potentially saving millions of lives, dramatically enhancing economic productivity, and facilitating achievement of Millennium Development Goal #4 (reducing under-five mortality by two-thirds by 2015). Member companies contribute to DoV objectives through their R&D and access programs.

2.1. Research and development

A major area in which the members of IFPMA and BIO contribute to the DoV vision is through their pipelines of innovative vaccines. During the last 30 years, vaccine development has accelerated due to improved understanding of microbial pathogenesis and the human immune response [4]. Table 1 reviews recently introduced vaccines.

Biopharmaceutical companies continue to make significant investments to enhance the programmatic effectiveness of current products and to extend the range of available vaccines. This includes research on vaccines to prevent infectious diseases that disproportionately affect the developing world, such as HIV/AIDS, malaria and tuberculosis, as well as vaccines to treat non-infectious diseases such as cancer. Table 2 provides an overview of vaccines in development by research-based vaccine companies.

Vaccines currently represent a major portion of R&D projects dedicated to neglected diseases. According to a recent survey [11]:

- Of the 374 products currently in development for neglected diseases, 201 (54%) are vaccines targeted to 16 specific neglected diseases or diseases that disproportionately affect the poorest countries.
- Many of the most prevalent diseases, such as malaria, tuberculosis, dengue, leishmaniasis, shistosomiasis, cholera, and pneumoccocal infections, have multiple vaccines in various stages of development [12].
- Forty percent (40%) of the R&D under way for neglected diseases is conducted through product development partnerships (PDPs).
- 13 large pharmaceutical companies are participating in the development of 65 (17%) drugs or vaccines for neglected diseases, with their involvement substantially higher at later stages, especially Phase III.
- Smaller biotech companies are participating in the development of 85 (42%) of the vaccines included in the analysis, and are generally focused on early stage development from discovery through Phase I – although, increasingly, those companies are actively engaged through Phase II research.

Vaccine scientific breakthroughs often are the result of collaborations between large companies, smaller biotechnology enterprises, and other partners from academia and the public sector. These collaborations can take the form PDPs [13], such as:

- International AIDS Vaccines Initiative (IAVI);
- Aeras (focused on tuberculosis vaccines); and
- Sabin Vaccine Institute.

These partnerships are centered around the simultaneous pursuit of multiple vaccine candidates for a particular disease category – thereby supporting innovation and collaboration, securing future vaccine supply and access, and promoting the introduction of competing vaccines in the marketplace.

2.2. Access

In addition to researching and developing innovative vaccines, the industry also contributes to enhanced vaccine access, through:

- Individual company programs including public–private partnerships, donations, and training programs for health care providers.
- Participation – for over a decade – as a partner in the GAVI Alliance – a public–private partnership dedicated to making needed vaccines available in the developing countries.
- Engagement in global initiatives to improve immunization supply and logistics systems (e.g. WHO "Project Optimize") or to address the unique constraints of developing country cold chain