

Innovative Vaccines Companies and the Decade of Vaccines

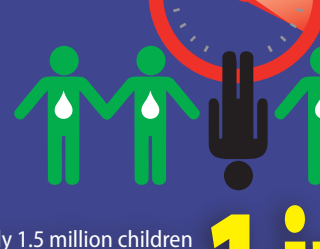
2010 2020+



The goal of the Decade of Vaccines (DoV) initiative, launched in 2010, is 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"

1 in 5

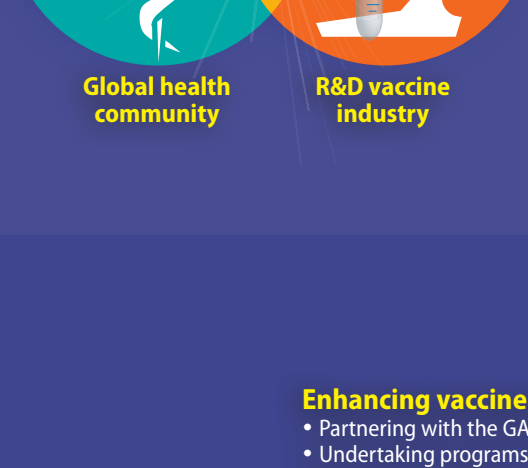
One in five children worldwide does not receive the most basic vaccines



Nearly 1.5 million children die each year—one every 20 seconds—from vaccine-preventable diseases

1 in 20"

What will it take to sustainably deliver high quality new vaccines?



Existing life-saving vaccines and the new ones that are in the pipeline are the result of years of work by research-based vaccine industry. This fact plus a long-standing track record of success and specialized expertise uniquely position vaccine companies to help deliver the promise of the DoV initiative. While the global health community sets the strategy and goals for the DoV, industry can help explain what it is required, from an experienced perspective, to maintain momentum on vaccine innovation, manufacturing and supply.



25

vaccine-preventable infections

50

life-threatening diseases in the pipeline



Enhancing vaccine access

- Partnering with the GAVI Alliance: 5 million lives saved in the past 10 years
- Undertaking programs including public-private partnerships, donations and training
- Engaging to improve immunization supply and logistics systems

Partnering

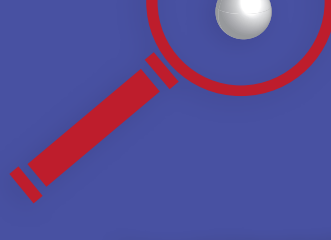
Undertaking programs

Engaging

Our challenges

Vaccine R&D is a complex, arduous, expensive and high-risk venture:

A vaccine is to be widely-used in the general population for disease prevention



A vaccine is a complex biological product made from living organisms with a natural tendency to change.

There is no "one size fits all" vaccine type; vaccines are composed of either the entire disease-causing microorganism (inactivated) or some of its components and are mixed with other fluids (such as water or saline), additives or preservatives, and sometimes adjuvants to ensure the quality and potency of the vaccine over its shelf-life



Vaccine R&D involves identifying new antigens but also setting up innovative manufacturing processes, quality controls procedures, and the entire technical platform needed to measure the immune response and ensure rigorous long-term quality and safety monitoring

R&D

USD200-900 millions

8-18.5 years

Development of new vaccines is costly and complex; it can cost from USD 200 to 900 million and it can take from 8- to 18.5 years.



Regulatory

Companies must demonstrate to regulatory authorities that a vaccine is safe, effective and always of the same high quality.

Key stages:

- Identification of key antigen and its composition
- Clinical studies (phase I, II, III) conducted with up to 100,000 volunteers
- Comprehensive dossier submitted to health authorities to prove that the candidate vaccine is safe and effective
- Dossier subject to intense review by health authorities
- Once a marketing authorization is granted, systems for pharmacovigilance to detect and report any adverse reactions
- Marketing authorization must then be maintained and updated with new information reflecting any changes in the manufacturing process or updates to the prescribing information. This requires «amendments» to be submitted for the health authority for their review and approval prior to implementation. The entire regulatory process is managed on a country-by-country basis which results in thousands of regulatory submissions during the products lifecycle

Safe

Manufacturing

5 years

USD600,000

A new biological manufacturing site can cost as much as USD 600,000 and take 5 years to build and validate.

The vaccine manufacturing process is complex as vaccines are based on living organisms; more than 500 quality control tests may be conducted in the manufacture of a single batch vaccine.



Demand forecast



Anticipating future disease and healthcare dynamics, forecasts can carry significant variability.

Our recommendations

The innovative vaccine industry is well positioned to:

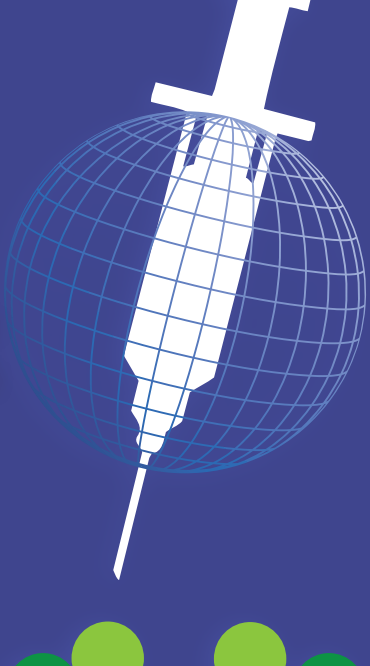
Participate in open dialogue with countries and other international stakeholders to ensure sustained access to current and future high-quality vaccines, by working jointly to address technical, regulatory and economic challenges

Advance innovation in R&D, vaccine delivery, and manufacturing

Objective 1

All countries commit to immunization as a priority

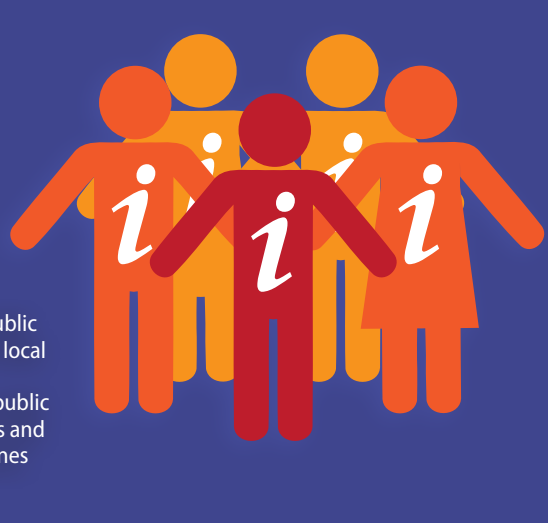
- Sustain progress in the prevention and treatment of infectious diseases
- Improve epidemiological data to help societies to appreciate the full benefits of vaccination
- Eliminate silo mentality of health services by incorporating into budgetary decision making a wider recognition of the positive effects of prevention on socio-economic development



Objective 2

Right and responsibility of individuals and community

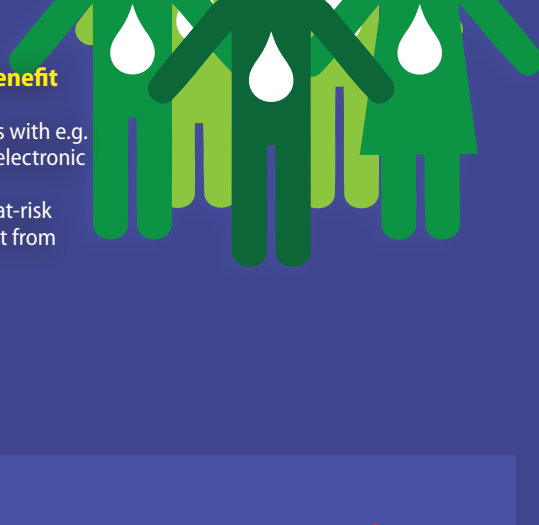
- Provide information to the general public on immunization taking into account local conditions and perceptions
- Conduct research to better measure public sentiment and understand the drivers and barriers to public acceptance of vaccines



Objective 3

Benefits of immunization should benefit everybody

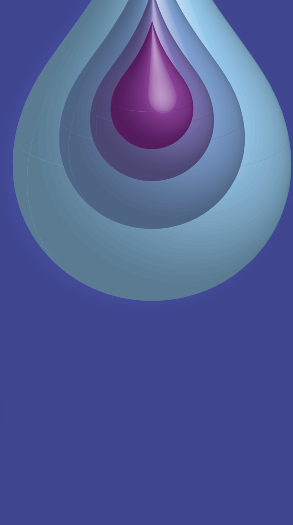
- Use IT to reach underserved populations with e.g. immunization registries, checklists and electronic databases
- Continue "life course" approach to help at-risk population in every age group to benefit from immunization



Objective 4

Strong immunization systems

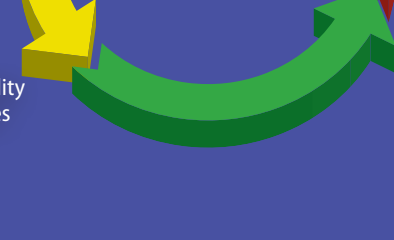
- Promote national ownership of immunization
- Strengthen routine immunization
- Reinforce the disease surveillance
- Support greater coordination among existing vaccination programs at the country level by providing greater clarity regarding national immunization priorities, and optimizing resource
- Provide greater opportunities for shared learning among developing countries, building on forums provided by GAVI, UNICEF and WHO



Objective 5

Ingredients of viable immunization programs

- Recognize and maintain the market-based incentive structure that enhances the affordability of needed vaccines, while maintaining incentives for future R&D of innovative, quality vaccines including:
 - sustainable financing
 - differential pricing
 - predictable demand and consistent uptake
 - consistent high quality standards in order to guarantee equal quality products
 - solid IP protection



Objective 6

Boosting country, regional and global R&D

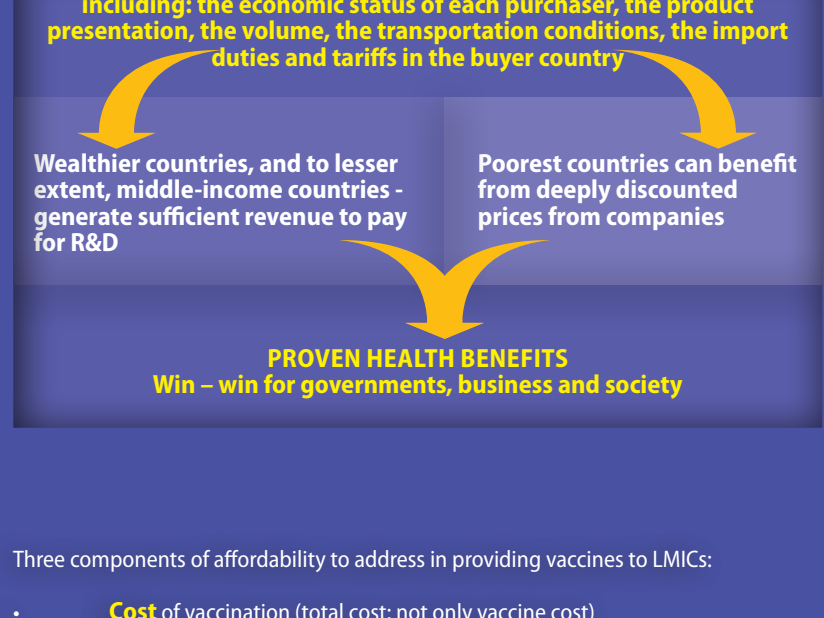
- Increase financial incentives to support ongoing R&D to combat neglected diseases – employing a combination of R&D "push" and "pull" mechanisms to support early and late stage research
- Ensure that "push" and "pull" mechanisms are structured in such a way as not to create a monopolistic situation, discouraging suppliers from entering the market
- Promote greater dialogue between vaccine companies and developing countries, to ensure that developing country needs are reflected in company research portfolios



Affordability

Key ingredient of a viable immunization program

Maintaining effective immunization programs requires a multifaceted approach of balancing funding, affordability, quality, and security of supply in a manner that advances sustainable engagement of all key stakeholders.



Three components of affordability to address in providing vaccines to LMICs:

- **Cost** of vaccination (total cost; not only vaccine cost)
- **Availability** of funds
- **Willingness** to commit funds to immunization programs

Differential pricing has allowed greater access to vaccines for people and is recognized as a critical element to improving vaccination levels in low- and middle-income countries (LMICs). But differential pricing is coming under challenge, with some stakeholders advocating a formula linking vaccine prices for the LMICs to those offered through the GAVI Alliance, and with the GAVI proposing development of criteria for pricing tiers. Externally imposed formulas for pricing or for pricing tiers would interfere with the competitive market forces that have to date supported sustained investment in innovation.



Boosting R&D

To expand and accelerate innovation in new vaccines, especially in the developing world, financing solutions are needed that both "push" and "pull" investment.

Together "push" and "pull" mechanisms can create:

- more attractive markets
- lower uncertainty
- support return on investment
- thereby stimulating increased R&D investment

Push mechanisms: grants, subsidized loans, investment tax credits

- Fund R&D directly
- Public-private partnerships aimed at developing new vaccines adapted to needs of development markets

Pull mechanisms: donors stimulate demand for new technologies through purchase commitments and volume guarantees

- Incentivize R&D by creating market certainty and lower risk



The innovative vaccine companies look forward to continuing the dialogue with the other DoV stakeholders