GSK and the Decade of Vaccines

The Decade of Vaccines Collaboration and the Global Vaccine Action Plan

A guide to GSK’s contribution to the global initiative, known as the Decade of Vaccines, to extend access to immunisation to everyone in the world, promote innovation in the vaccines industry and prevent millions of deaths.

The Decade of Vaccines (DoV) is guided by a collective vision in which people everywhere enjoy lives free from vaccine preventable illness. Since its inception in 2010, much has been done to turn this vision into reality.

Formed in 2011, the Decade of Vaccines Collaboration (DoVC) is an unprecedented effort led by some of the most influential members of the global health community: the World Health Organization, the African Leaders Malaria Alliance, the Bill & Melinda Gates Foundation (BMGF), the GAVI Alliance (the Global Alliance for Vaccines and Immunisation), UNICEF, and the U.S. National Institute of Allergy and Infectious Diseases. Partners in this multi stakeholder approach included governments, policymakers, elected officials, NGOs, health professionals, global development organisations, other development partners, the research community and vaccine manufacturers.

Later the same year, the DoVC and its partners began work on a plan for the rest of the decade, known as the Global Vaccine Action Plan (GVAP) which includes a set of key objectives and specific immunisation goals for the developing world and a guide for achieving them.

In May 2012, at the 65th World Health Assembly, all 194 member states of the World Health Organization endorsed the plan.

“This decade will help realize the full power of immunisation to prevent morbidity and mortality”

Dr Margaret Chan, Director-General of the World Health Organization.

The GVAP has six strategic objectives:

- Individual countries should have primary responsibility for providing effective and quality immunisation services for all and it wants all countries to commit to immunisation as a priority;
- Immunisation is an individual, community and governmental responsibility that transcends borders and it wants individuals and communities to understand the value of vaccines and to demand immunisation as both their right and their responsibility;
- Equitable access to immunisation is a core component of the right to health and it wants the benefits of immunisation to be equitably extended to all people;
- To be effective, immunisation needs to be closely coordinated with health systems and other primary healthcare delivery programmes and it wants strong immunisation programmes to be an integral part of broader healthcare systems, the world over;
- To be sustainable, immunisation programmes require informed decisions, informed implementation strategies, improved financial management, improved oversight and appropriate levels of financial investment and it wants immunisation programmes to have access to quality supply, innovative technologies and predictable funding;
- There needs to be a greater focus on quality, education and innovation if immunisation programmes are to realise their full potential to save and improve lives and it wants targeted and innovative R&D at the discovery, development, manufacture and delivery stages and at the country, regional and global levels

It is an ambitious plan. However, it is also detailed, carefully considered and, above all, achievable.

GSK fully endorses the plan. We believe it is imperative to do everything we can to support it.
The GVAP goes to the heart of our mission at GSK, to improve the quality of human life by enabling people to do more, feel better and live longer.

For manufacturers, the GVAP sets out eight imperatives:

1. To continue to develop, produce and supply innovative and high quality vaccines that meet countries’ needs;
2. To support research and an education agenda for immunisation;
3. To participate in open dialogues with countries and the public sector to ensure sustainable access to current and new vaccines;
4. To continue to innovate manufacturing processes and pricing structures;
5. To support the media outreach for the Expanded Programme on Immunization to increase awareness;
6. To support rapid scale-up and adoption as new or improved vaccines emerge;
7. To develop partnerships that support the growth of manufacturing capabilities and increase vaccine supply and innovation;
8. To work in coordination with other partners on vaccine and immunisation advocacy.

The GVAP’s imperatives are a call to action for vaccine manufacturers, which we have actively embraced.

So, what are we doing?

We have made commitments to our stakeholders in four key areas, each of which relates to one or more of the GVAP’s imperatives:

1. **Access**: making our vaccines available to as many people who need them as possible; in one way or another, all of the GVAP’s imperatives relate to the issue of access;
2. **Innovation**: innovating where it really counts, in line with imperatives 1, 4 and 7, we invest in research and development to create new vaccines that meet real healthcare needs around the world;
3. **Quality**: staking our reputation on the quality of our vaccines; we are committed to the highest standards of quality in everything we do; the GVAP is right to emphasise the importance of maintaining quality in its first imperative;
4. **Collaboration**: partnering widely with others to improve access, to innovate and to enhance the quality and efficacy of vaccines and vaccination, in line with imperatives 7 and 8.

**GSK is one of the world’s largest manufacturers of vaccines**: in 2012 we supplied 21% of the global vaccine market. In 2013, we distributed over 860 million doses of vaccines to some 170 countries. Around 40% of the world’s children are immunised against at least one serious disease with a GSK vaccine.

**GSK is one of the world’s most innovative developers of vaccines**: we have a portfolio of over 30 vaccines – the most comprehensive range of any company - and a pipeline of 16 candidate vaccines.

**40%**

Around 40% of the world’s children are immunised against at least one serious disease with a GSK vaccine.

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1. Access

Our drive to make vaccines available to everybody who needs them, wherever in the world they live, is at the heart of our business strategy

Every year, vaccines prevent some three million deaths and save some 750,000 children from disability. Only clean drinking water rivals vaccination in its ability to save lives.

However, too many are still not getting the vaccines they need. Despite the achievements of the last 50 years, around 22 million children in developing countries still don’t have access to life-saving vaccines. As a result, some 19,000 children under five die every day from largely preventable causes, two thirds from infectious diseases such as pneumonia, diarrhoea and malaria. Many of these children might still be alive today if they had been vaccinated. There are some tough challenges in healthcare today including:

- Reaching those still dying from preventable disease;
- Re-emerging killer diseases such as measles and polio;
- Competing priorities in developing countries with often weak health infrastructure and budgetary constraints.

We are investing our substantial resources and working with others to help tackle these access challenges:

- No other company makes such a wide range of vaccines available to so many countries worldwide;
- UNICEF purchases vaccines on behalf of GAVI and the Global Polio Eradication Initiative and we are UNICEF’s primary supplier;
- 80% of the vaccine doses we manufactured in 2013 went to developing countries;
- In 2012, for the third successive time, we were placed at the top of the Access to Medicines Index, which measures the performance of the 20 leading pharmaceutical companies in providing access to medicines, vaccines and healthcare in developing countries.

We refuse to be complacent. We are always seeking to improve and to find innovative ways of doing things better and investing to ensure that we do.

As part of our drive to improve access, we have prioritised two things in particular: equitable pricing (the way in which we charge countries for our vaccines, recognising different levels of development) and sustainability of supply (to ensure that we can meet demand for them over the long term).
No other company makes such a wide range of vaccines available to so many countries worldwide.

30.5m

We estimate that in 2012, our vaccines helped prevent 30.5 million infections in GAVI-eligible countries.

Tiered Pricing

We are determined to use our resources, knowledge and expertise to help improve access to immunisation for people everywhere. At the same time, we are determined to keep our business sustainable so that we can research and develop and reliably supply effective, high quality vaccines. This is why, for over 20 years, we have adopted a tiered pricing system for our vaccines and evolved that approach to recognise changes in global development and encourage pro-vaccination policies.

Our tiered pricing approach asks countries, at each step along their development journey, to pay a fair price: in other words, a price they can afford and which reflects their particular circumstances.

Our approach is designed to support those countries which commit to vaccination for the long term and implement programmes aimed at reaching large proportions of the target population.

Tiered pricing reflects the fundamental value of immunisation as an investment in health. It also reflects our desire to enable countries to maintain and expand upon their commitment to immunisation as their economies grow.

For the least well-off countries, we also work closely with GAVI and UNICEF to improve access to vaccines. These organisations are able to purchase large volumes of vaccines for the world’s poorest children at our lowest prices.

It should be noted that the benefit of vaccines to low- and middle-income countries over the next 10 years is estimated at around US$150 billion. According to a Harvard University study, the investment by the GAVI Alliance alone in immunisation will yield an 18% return on investment by 2020.

Sustainability of supply

Today, we are the primary supplier of vaccines to UNICEF which purchases vaccines on behalf of GAVI and the Global Polio Eradication Initiative.

To meet countries’ growing needs for high quality vaccines for decades to come, we are investing in new manufacturing facilities and partnerships around the world, investing in manufacturing processes and transforming our business to enable us to deliver tailored solutions.

For example:

• To meet our obligations under the Advanced Market Commitment, through which we supply GAVI with our vaccine against pneumococcal disease, we have invested more than US $400 million in a dedicated manufacturing plant in Singapore that will support growing demand for this vaccine in the coming years;

• To meet demand from GAVI, we are implementing two new production lines for our rotavirus vaccine;

• To improve the distribution of our vaccines to customers around the world, we have established secondary sites in China, India and Russia;

• To provide vaccines that address public health priorities in Brazil, including Hib (Haemophilus influenzae B), MMR (measles, mumps and rubella) and MMRV (measles, mumps, rubella and varicella), we have created local manufacturing facilities in partnership with FioCruz, a Brazilian pharmaceutical company with which we have a long and successful history of collaboration;

• To produce vaccines containing Inactivated Poliovirus Vaccine (IPV) for developed and emerging markets in the post-polio eradication phase, we are investing around £250 million in a new IPV manufacturing facility and have launched a new joint venture with Biological E, the Indian biotechnology company, for the research and development of a six-in-one combination vaccine containing IPV.

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2. Innovation
We will continue to invest in the discovery, development, manufacture and delivery of vaccines

1,600
We have 16 candidate vaccines in our pipeline and 1,600 scientists working to develop new vaccines and improve existing ones.

30
Today, we have a portfolio of more than 30 vaccines.

£496m
We invested £496m in core vaccine research and development in 2013.

GSK is a leader in vaccine innovation.

Eleven times in our history, we have created the world’s first vaccine of its kind. We developed the world’s first vaccines for rubella (1969), varicella (1984), recombinant hepatitis B (1986), hepatitis A (1992), combined hepatitis A & B (1996) and a variety of innovative combined vaccines.

Today, we have a portfolio of more than 30 vaccines. These include our vaccines against cervical cancer, rotavirus and pneumococcal disease, each of them highly innovative and each supported by GAVI.

We are the only manufacturer to be able to supply GAVI with vaccines against these three diseases.

By 2015 GAVI hopes to immunise 250 million children against pathogens known to cause pneumonia, meningitis, enteritis and diarrhoea and more than 30 million girls in over 40 countries are expected to receive vaccination to help protect them from cervical cancer by 2020.

Our vaccines will be critical in helping GAVI reach these targets.

We have 16 candidate vaccines in our pipeline and 1,600 scientists working to develop new vaccines and improve existing ones. GSK invested £496 million in core vaccine research and development in 2013.

Today, we are focusing on two areas of particular importance to global public health:

• Priority diseases, for which no vaccine yet exists such as malaria, HIV, tuberculosis and dengue fever; and
• Adapting vaccines to the multiple storage and transit environments they will encounter, especially in the developing world, and in particular addressing cold chain challenges, i.e. challenges relating to storage temperature all along the supply chain.

In addition, we are investing in:

• Researching and developing adjuvants, substances that enhance the body’s immune response to a vaccine; and
• Innovative development platforms designed to facilitate major advances in the science of vaccines.

Priority Diseases

Malaria – In 2012, around 627,000 people died from malaria, most of these were African children under the age of 5.

GSK has been working in partnership with scientists around the world to develop a vaccine against malaria for the past 30 years, investing US $350m to date in this effort. Our vaccine candidate - RTS,S - is being developed in partnership with PATH Malaria Vaccine Initiative (MVI), with grant monies from the Bill & Melinda Gates Foundation to MVI. It is currently in phase III trials and we plan to submit a regulatory application to the European Medicines Agency (EMA) in 2014. If a positive scientific opinion is granted the World Health Organization has indicated a policy recommendation for the RTS,S vaccine candidate could be possible by the end of 2015, paving the way for local regulatory submissions and decisions by African nations regarding large-scale implementation of the vaccine through their national immunisation programs. If approved, RTS,S will be the world’s first ever licensed vaccine against malaria.

HIV - In 2012 there were an estimated 35.3 million people living with HIV.

Our HIV vaccine candidate, which we are developing jointly with the International AIDS Vaccine Initiative (IAVI) under a Product Development Partnership (PDP) agreement, is undergoing phase II trials.

Tuberculosis – Our TB vaccine candidate, on which we are collaborating with Aeras, under another PDP agreement, is also currently undergoing phase II trials. Aeras is a non-profit biotech seeking to advance the development of new TB vaccines.

Dengue fever - We have had a long and successful manufacturing partnership with Fiocruz in Brazil, focusing on priority diseases. We have now started to collaborate on vaccine development. Scientists from GSK and Fiocruz are working together in both Brazil and Belgium to develop a candidate vaccine against dengue fever.
of our new candidate vaccines in development target diseases particularly prevalent in the developing world, including all three WHO infectious disease priorities: HIV, malaria and TB28.
3. Quality

GSK will continue to deliver vaccines of the very highest quality wherever in the world they are needed.

Vaccines are complex both to develop and to produce and require considerable investment over a long period of time. We will continue to invest heavily and consistently in both R&D and manufacturing in order to ensure that our vaccines are safe and effective. We will never compromise on the quality of our vaccines.

Vaccine development

We work in compliance with the rigorous regulatory requirements of the European Medicines Agency and the U.S. Food and Drug Administration.

For example, to obtain a worldwide license for our rotavirus vaccine, we carried out over 15 separate studies. These involved more than 90,000 infants, 50,000 of whom received the vaccine.

Rigorous, large and complex clinical studies are not unique to rotavirus. GSK invested in over 15 years of complex development before our vaccine against pneumococcal disease was licensed.

Vaccine manufacture

Our manufacturing sites and processes adhere to the strictest regulations and guidelines; we invest, innovate and inspect on a constant basis to ensure that they remain so:

- We have one standard for all vaccines regardless of where they will be used in the world;
- We ensure, prior to their release, that all our vaccines have been manufactured in accordance with World Health Organization standards;
- Every batch of our vaccines is approved, when required, by relevant authorities in the country in which it will be used; approval is based on samples submitted to official laboratories;
- We check quality throughout the production process: our people, our manufacturing facilities and equipment and all components of all our vaccines.

860m

In 2013, we distributed over 860 million doses of vaccines to some 170 countries.

520

Batches of the most complex vaccines, such as our vaccine against pneumococcal disease, go through as many as 520 tests.

We believe strongly in rigorous quality assurance and control. Every year, we conduct no fewer than 120 internal audits of our manufacturing sites. To put it another way, at each site 10 working days in any given year will be internal audit days.

860m

In 2013, we distributed over 860 million doses of vaccines to some 170 countries7.

520

Batches of the most complex vaccines, such as our vaccine against pneumococcal disease, go through as many as 520 tests31.
4. Collaboration

We are partnering with research organisations, academic institutions, NGOs, governments and other manufacturers to improve access, encourage innovation and to enhance the quality and efficacy of vaccines and vaccination.

90%

more than 90% of the vaccines in our pipeline are being developed in partnership with others.

100

We maintain over 100 partnerships in R&D alone.

Research and development

Right across our R&D organisation, we form partnerships with third parties to exchange ideas, share knowledge and accelerate the discovery and development of new vaccines. We have written about work with Aeras, which is based in North America, China and South Africa, Biological E in India and Fiocruz in Brazil. We have numerous active projects and/or collaborations with the Bill & Melinda Gates Foundation, the International AIDS Vaccine Initiative and the Malaria Vaccine Initiative at the Partnership for Appropriate Technology in Health (PATH).

We believe partnerships with academic institutions, foundations, and research organisations will help us to better tackle some of the toughest challenges facing global immunisation. In fact, more than 90% of the vaccines in our pipeline are being developed in partnership with others.

Access and education

We also have partnerships in the field of access and education, some global or international, some in individual countries.

GSK is a truly global company with an enormous range of products. In addition to our key research and development centres, we have a network of 87 manufacturing sites and operate in more than 115 countries. We are well placed to engage with governments and public sector bodies all over the globe and do so all the time. Engagement of this kind is invaluable in striving to improve access.

Just as important, however, are our close, productive and often long-established working relationships with global agencies, development partners and NGOs at the forefront of the drive to improve access to essential vaccinations for all who need them.

Some important partnerships

Agence de Médecine Preventive (AMP), WHO - In 2013, we announced that we would provide 25 scholarships, over three years, for training in health logistics via the joint AMP-WHO Logivac project and 25 further scholarships for AMP’s SURVEA training course in field epidemiology in Africa.

GAVI – Since its inception in 2000, we have collaborated with GAVI on activities ranging from research and development to delivery and education. We supply GAVI with vaccines against cervical cancer, rotavirus and pneumococcal disease. Our malaria vaccine candidate is included in GAVI’s future Vaccine Investment Strategy (VIS).

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Network for Education and Support in Immunisation (NESI) - For more than ten years, GSK has given an unrestricted education grant to NESI whose mission is to provide education, training and support in immunisation, to improve the quality and sustainability of immunisation programmes and services in low- and middle-income countries and to ensure better health for infants and children.

PULSE – Our PULSE Volunteer Partnership scheme lends GSK employees to non-profit organisations for up to six months at a time, giving them the opportunity to develop their professional skills in challenging environments, whilst sharing their strategic, operational and communications expertise with key partner organisations. Since 2009, GSK has worked with 85 PULSE partners in 57 countries, supporting non-profit organisations and Civil Society Organisations working on healthcare access and children’s issues.

Save the Children - In 2013, GSK embarked on a global partnership with Save the Children, which has been given a seat on a newly-created paediatric research and development board, intended to save the lives of a million of the world’s poorest children. As far as vaccines are concerned, the partnership’s principal purpose is to leverage Save the Children’s expertise and on-the-ground experience to widen access in the developing world, in particular to the poorest or most remote or marginalised children.

UNICEF - We have been in a partnership with UNICEF to ensure access to its vaccines in the developing world ever since our first OPV, over 50 years ago. Since the establishment of the Global Polio Eradication Initiative in 1988, we have supplied nearly 16 billion doses of OPV. We are committed to meeting a third of UNICEF’s polio vaccine requirements over the next three years.

Vodafone: GSK has formed a partnership with Vodafone to harness innovative mobile technology to help vaccinate more children in Africa. This initiative is designed to encourage mothers to take up vaccination services, to support health workers, to improve record keeping and to enable better management of vaccine stocks.
Looking to the future

7x increase

As part of our drive to improve access, we plan to increase sevenfold, in the next several years, the volume of vaccines we supply to GAVI.

Vaccines help save and improve the lives of countless millions of people. Discovering, developing, manufacturing and selling vaccines carries with it significant responsibility. That’s why we’re committed to playing our part in the Decade of Vaccines and beyond: continuing to put the people we help protect with our vaccines at the heart of our business; innovating and finding new ways of doing things; maintaining standards of the very highest quality; and, on a constant basis, making our business more flexible, more responsive and more competitive.

**Immunisation is a matter of justice**, said Dr. Seth Berkley of the GAVI Alliance. We agree. We are working towards a world in which everyone has access to vaccines and can be protected against life-threatening disease. By continuing our commitments to access, innovation, quality and collaboration we want to help people do more, feel better and live longer.

“It’s absolutely crucial that both governments and the private sector step up efforts to provide life-saving vaccines to children who need them most!”

Dr Margaret Chan, Director-General of the World Health Organization.

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4 GSK data on file.
6 Internal data, referenced July 2013.
12 Low, low middle income, and middle income countries. The World Bank classifies economies according to their Gross National Income (GNI) per capita in 2012. Low-income countries (LICs) have an annual GNI per capita of less than US$1,035. Middle-income countries (MICs) have an annual GNI per capita of US$1,036 - US$12,615. High-income countries (HICs) have an annual GNI per capita of US$12,615 or more.
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