

Following impressive clinical trial results, we have filed our candidate shingles vaccine with regulators in the US, Canada and Europe.

Vaccines



We have the broadest vaccines portfolio of any company, with vaccines for people of all ages – from babies and adolescents to adults and older people.

Strategic report

Governance and remuneration

Financial statements

Investor information



Grow



£4.6bn

Vaccines sales were up 26% AER and 14% CER^a (12% pro-forma CER) in 2016 with growth across the US, Europe and International markets.

Deliver



14

In 2016, we filed our candidate shingles vaccine, *Shingrix*, and have 14 candidate vaccines in our pipeline for a range of diseases.

Simplify



>30%

Operating profit margin was 31.7% in 2016, 5.3 percentage points higher than in 2015 and 7.6 percentage points higher on a CER pro-forma basis.

Responsible business



We are working with partners to help the world be better prepared for global health epidemics.

Footnote

^a We use a number of adjusted, non-IFRS, measures to report the performance of our business, as described on page 67, including core results, free cash flow and CER and pro-forma growth rates. Non-IFRS measures may be considered in addition to, but not as a substitute for or superior to, information presented in accordance with IFRS.

Vaccines

Our Vaccines business is one of the largest in the world, delivering over two million doses of vaccines per day to people in over 160 countries.

Our Vaccines business has a portfolio of 41 paediatric, adolescent, adult, older people and travel vaccines that offer protection against 22 different diseases. These include *Bexsero*, our meningitis B vaccine; *Menveo* for meningitis A, C, W and Y; Flu; Hepatitis; *Synflorix* for pneumococcal disease; *Rotarix* for rotavirus gastroenteritis; and vaccines against diphtheria, tetanus and whooping cough, namely, *Infanrix/Pediarix* and *Boostrix*.

Demand for vaccines continues to increase as the world's population grows and changes. To meet this demand, we must deliver reliable, high quality vaccines and push the boundaries of science and technology to develop innovative vaccines.

Behind our commercial portfolio is our robust research pipeline, which reflects our expertise in virology and bacterial infection, and across different technological platforms. We have more than 2,000 scientists dedicated to discovering and developing vaccines across our three global R&D centres in the US and Europe. As well as our internal research, we have more than 180 R&D partnerships with external scientists and leading academic and public health institutions.

To help more people benefit from vaccine protection, we use a 'tiered pricing' approach, based on nations' gross national income per head and ability to pay. We are also one of the largest contributors to Gavi, the Vaccine Alliance, a public-private partnership that aims to improve access to vaccines in developing countries.

Candidate shingles vaccine filed



Following impressive clinical trial results, we have filed our candidate shingles vaccine *Shingrix* with regulators in the US, Canada and Europe.

We are seeking approval for *Shingrix*, our candidate vaccine, for use in preventing shingles – a common but potentially serious condition – and its complications in people over 50. Shingles sufferers develop a painful itchy rash, with up to 30% also getting postherpetic neuralgia (PHN), an intense pain that can last for at least three months.

More than one in three people over 50 are likely to have shingles in their lifetime. Individuals with compromised immune systems, such as cancer patients undergoing chemotherapy, are especially susceptible.

A study published in 2016 found *Shingrix* had 90% efficacy for people over 70, maintained for up to four years, while earlier research showed 97% efficacy in those over 50.

This is the first time such high efficacy has been demonstrated in a candidate vaccine for older people, whose weakened immune systems often leave them more susceptible to disease. There is a possibility therefore that the technology it is based on may open up effective treatments for other conditions affecting older adults.

In 2017, we expect the results of clinical studies with *Shingrix* both in people at high risk of shingles, due to the weakening of their immune systems, and in patients revaccinated with our candidate vaccine who have previously received the existing vaccine.

Grow

Vaccines sales grew 14% on a reported basis (12% pro-forma) to £4.6 billion, from strong performance from our meningitis and flu vaccines.

All growth rates are at CER, a non-IFRS measure as described on page 57, unless otherwise stated.



2016 performance summary

Vaccines sales grew 26% at actual rates, 14% CER and 12% pro-forma CER to £4,592 million during 2016. Performance was driven by sales of new products including meningitis vaccines *Bexsero* and *Menveo* which contributed £592 million. There was also strong demand for *Fluarix /Flulaval* which had sales of £414 million.

US sales grew 13% (12% pro-forma) with *Bexsero*, *Menveo* and *Boostrix* all seeing market and share growth while *Infanrix* and *Pediarix* both benefited from competitor supply issues in the market.

In Europe, sales grew 18% (16% pro-forma), driven primarily by *Bexsero* sales through the UK Government's immunisation programme and in private market channels in several other countries. *Boostrix* sales in Europe benefited from higher demand and competitor supply issues.

Sales in International markets grew 10% (8% pro-forma), with growth primarily driven by *Synflorix*, due to market expansion in Asia and certain African countries. *Menveo* sales also contributed to growth driven by a significant tender award in Argentina. Vaccine sales increased in Brazil due to strong demand for *Bexsero*, *Menjugate* and *Boostrix*.

UK infants benefit from meningitis B vaccine



The number of cases of meningitis B reported in the UK fell significantly after babies were vaccinated with our *Bexsero* meningococcal vaccine.

The UK became the first country in the world to introduce a national infant immunisation programme against meningitis B in late 2015, with children being vaccinated at two and four months and receiving a booster at one-year-old.

Just ten months after the programme was launched, Public Health England (PHE) figures showed 83% percent effectiveness of *Bexsero* against meningitis B.

Invasive meningococcal B disease is the leading cause of meningitis in the industrialised world. It develops rapidly, typically among previously healthy children and adolescents. About one in ten of those who contract the disease die, with a further 20% suffering a major physical or neurological disability, such as limb or hearing loss.

Bexsero is the only meningococcal B vaccine licensed in Europe. In the past two years, the numbers of doses of *Bexsero* produced has grown from two million to a cumulative total of ten million.

Vaccines continued

Deliver

Our broad pipeline includes vaccines targeting shingles, meningitis, respiratory syncytial virus, group B streptococcus, and a new vaccine concept for COPD.



Our Vaccines R&D work focuses on discovering and developing vaccines to help protect people against a broad range of diseases and conditions across all age groups. We have a pipeline of 14 candidate vaccines in early, mid and late stage development against a range of diseases.

In 2016, we received regulatory approval to expand the indication for *FluLaval* in the US to cover infants from six months of age, rather than from three years. We obtained approval in Europe for a label update for *Boostrix* and *Boostrix Polio* with human safety data to support use in pregnant women. We also launched our *Hiberix* vaccine in the US.

In 2016, we filed for regulatory approval in North America and Europe for our candidate vaccine for the prevention of shingles and its complications. (See case study on page 30.) In 2017, we plan to file for its use in Japan.

We have a number of promising earlier assets in our pipeline. For example, the candidate vaccines in phase II, are for meningococcal A,B,C,W,Y, respiratory syncytial virus (RSV), group B streptococcus and exacerbations in chronic obstructive pulmonary disease (COPD).

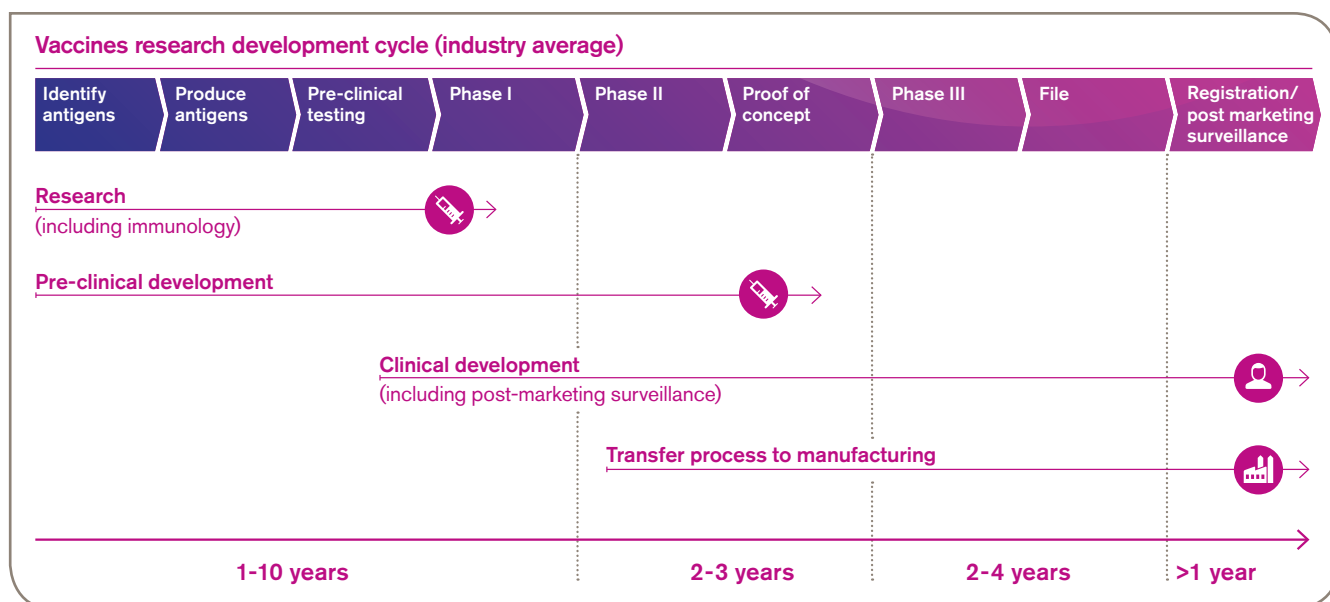
Following the positive scientific opinion from European regulators for our infant malaria vaccine *Mosquirix*, the World Health Organization will start pilot implementation of the vaccine in three sub-Saharan Africa countries in 2018. With our partners at the non-profit organisation PATH, we will donate doses of *Mosquirix* for the pilots.

In a bid to assist with the Zika virus, we are evaluating a new vaccine technology known as SAM (self-amplifying mRNA), with the National Institutes of Health. We believe this technology may potentially induce protective immunity against Zika.

Investment and governance

Our priorities are meeting patient needs and addressing global health challenges for which no vaccines yet exist, or where significant improvements could be made. Our vaccine R&D investment in 2016 was £597 million, up 2% from £525 million in 2015.

In R&D, we complemented our existing global hubs, in Siena, Italy and Wavre, Belgium, with the opening of a third centre, in Rockville, Maryland, close to our major US public health stakeholders. Our three global centres each have their own area of expertise in vaccine discovery and specific assets in development while also benefiting from scientific exchange between the three world-class teams.



Governance and remuneration

Financial statements

Investor information

Simplify

We have continued to simplify our operating model and realised significant savings.



In 2016, we continued to further simplify our operating model, strengthen our manufacturing network, and reduce supply costs.

During the year, we completed the majority of the Novartis Vaccines business integration. Cost savings generated in the Vaccines business have contributed to the delivery of £3 billion of annual savings for the Group by the end of 2016 (including £0.2 billion currency benefit). These savings, combined with strong sales growth, delivered improved operating leverage and a profit margin of 31.7%. This was 5.3 percentage points higher than in 2015 and 7.6 percentage points higher on a pro-forma CER basis.

Investing in our supply chain

We have 16 vaccine manufacturing sites in 11 countries. This international presence enables us to manufacture our vaccines with greater capacity, efficiency and flexibility. We aim to keep critical production steps in-house wherever possible, and during the year we invested in new production facilities at our Marburg site in Germany. This will enable us to produce all of the active components of our *Bexsero* vaccine in-house, and adds a new mumps production line for our combined measles, mumps, rubella and varicella vaccine.

Committed to quality

The discovery and development of new vaccines is a complex process. Our vaccines are manufactured to the highest quality standards, according to current Good Manufacturing Practice (cGMP) regulations. In 2016, we had 45 regulatory inspections and thirty-eight had minor or no findings. In all cases, we worked with regulators to address their observations.

Responsible business



Preparing for public health emergencies

GSK is committed to helping whenever we can when public health crises occur.



When Ebola broke out in West Africa, we accelerated the development of our candidate Ebola vaccine and, following the outbreak of Zika, we employed our novel technology platforms to start a vaccine discovery programme with the US National Institutes of Health.

However, responding after a life-threatening disease surfaces is not enough. Vaccine research and discovery is a lengthy process, typically taking 10 to 15 years. To have the best chance to save lives, the global community has to prepare itself in advance.

For this reason, we are proposing to create a dedicated and permanent 'biopreparedness organisation' (BPO) at our Global Vaccines R&D Centre in Rockville. The planned facility would design, develop and manufacture new vaccines against potential public health threats,

with targeted pathogens selected and prioritised with guidance from independent experts. It would have dedicated and permanent R&D and pilot production facilities, and the capacity to respond rapidly to future global health emergencies.

The BPO would operate on a no-profit, no-loss basis, with funding from both governments and non-governmental organisations.

We also strongly support the Coalition for Epidemic Preparedness Innovations (CEPI) and its focus on vaccines development as a solution to protecting against infectious disease outbreaks. We stand ready to partner with CEPI to advance epidemic preparedness.