# GSK VACCINES: KEY GROWTH DRIVERS

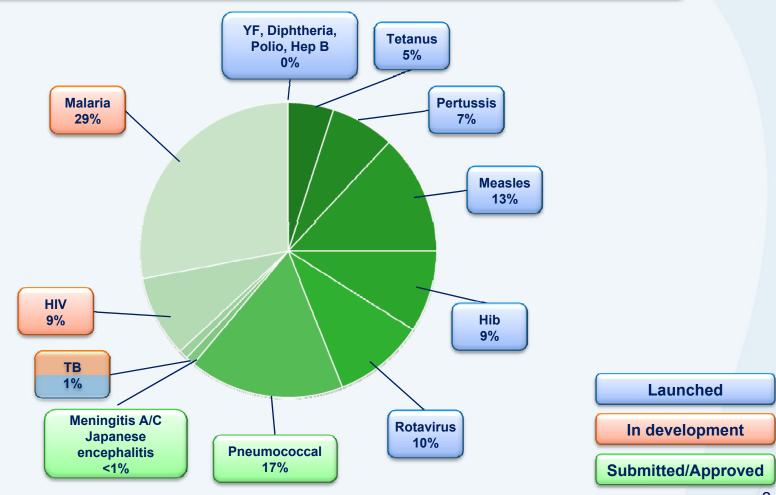
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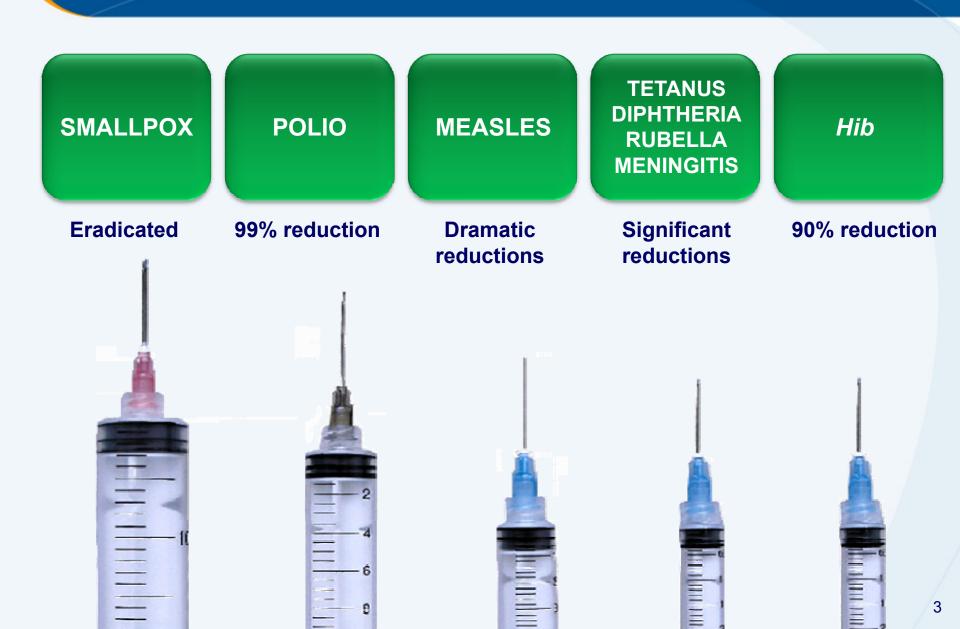


### Millions of children die from infectious diseases

Many of these deaths are preventable By 2015 vaccines could reduce these deaths by 90%



### What have vaccines achieved so far?



### **Economic benefits of vaccines**

In the **developing** world

- With the exception of clean drinking water, vaccines are the most costeffective public health measure<sup>1</sup>
- A 10-year gain in life expectancy translates into additional ~1% of annual growth of income<sup>2</sup>

In the **developed** world

- For each birth cohort vaccinated, the US saves<sup>3</sup>
  - \$10 billion in direct medical costs
  - \$33 billion in indirect costs

<sup>&</sup>lt;sup>1</sup> WHO IVB State of the World's Vaccines and Immunization. 3rd Edition, 2009

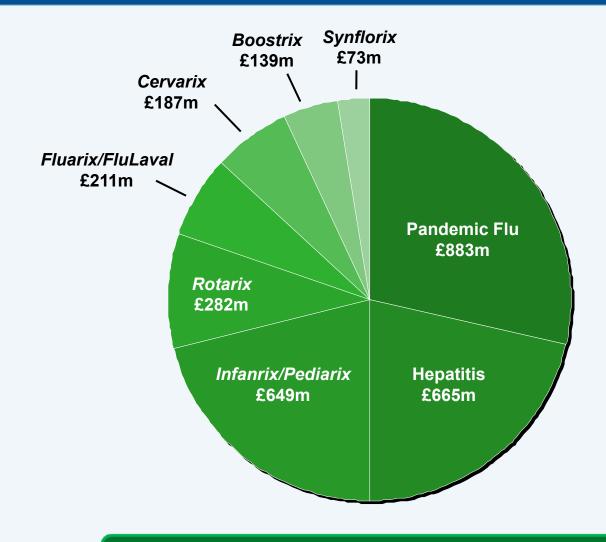
<sup>&</sup>lt;sup>2</sup> Bloom, ESPID May 2005

<sup>&</sup>lt;sup>3</sup> Roush & Murphy *JAMA* 2007; 298: 2155-2163

# GSK vaccines: fastest growing part of GSK in 2009

	2009 Sales	Share	Growth (CER)
Respiratory	£ 6,977m	25%	+5%
Consumer	£ 4,654m	16%	+7%
Anti-virals	£ 4,150m	15%	+12%
Vaccines	£ 3,706m	13%	+30%
CV & Urogenital	£ 2,298m	8%	+8%
CNS	£ 1,870m	7%	-44%
Anti-bacterials	£ 1,592m	6%	+2%
Metabolic	£ 1,181m	4%	-14%
Oncology & Emesis	£ 629m	2%	10%
Stiefel	£ 248m	1%	n/a
Other	£ 1,063m	4%	+1%
Total	£ 28,368m		+3%

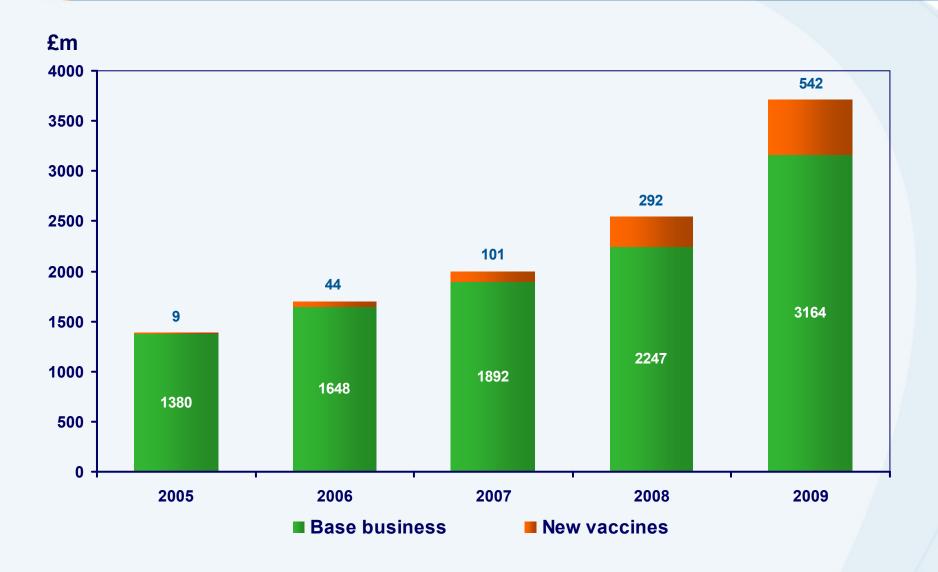
# **GSK** key vaccines: 2009 sales



2009 sales: £3.7 billion (+30%)

Growth rate is CER

# Growth of base vaccines business plus contribution of new vaccines



# GSK vaccines: current key growth drivers









### **PRODUCTS**

• Rotarix Approved 2005

Cervarix Approved 2007

• Synflorix Approved 2009

Boostrix Approved 2005

### **GEOGRAPHICAL**

- Emerging Markets
  - Annual growth of Emerging Markets 'middle classes' equivalent to population of UK
  - Annual birth cohort in China equivalent to population of Australia
- Japan
  - Underdeveloped vaccine market
  - Non-Japanese companies make up just 4% of vaccine sales
- US
  - Potential for increased market share

### Rotarix in 2010: continuing growth



**Approved in 116 countries** *Filed in Japan (November 2009)* 

2009 sales £282 million (Q1 2010 sales £65 million +19%)

Geographic expansion into EM & Japan US currently accounts for 60% of global market

WHO prequalification (June 2009)

Developing world data

Significantly reduced severe rotavirus gastroenteritis in African babies<sup>1</sup>

### Rotarix and PCV update

### Most frequently used rotavirus vaccine worldwide

- GSKs largest clinical trial programme (90,000 participants)
- Excellent safety & efficacy profile: over 71 million doses distributed

### March 2010: presence of PCV-1 material in Rotarix<sup>1</sup>

- PCV-1 does not multiply in humans and is not known to cause any illness in humans
- PCV-1 found in everyday pork products

### FDA requested suspension of use in the US (15 March – 17 May)

VRBPAC review of rotavirus vaccines (7 May)

### Key regulatory authorities supportive of continued Rotarix use

#### **FDA**

 "Benefits of vaccinating infants worldwide against rotavirus disease clearly outweigh the theoretical risks associated with the presence of PCV"

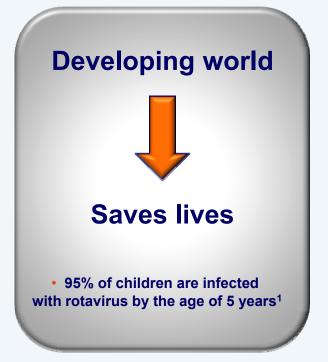
#### **EMA**

"No evidence that the presence of PCV in Rotarix presents a risk to public health and that there
is no need to restrict its use in the EU."

#### WHO

"WHO does not recommend any change to use of Rotarix vaccine"

### Rotarix: protection with two oral doses



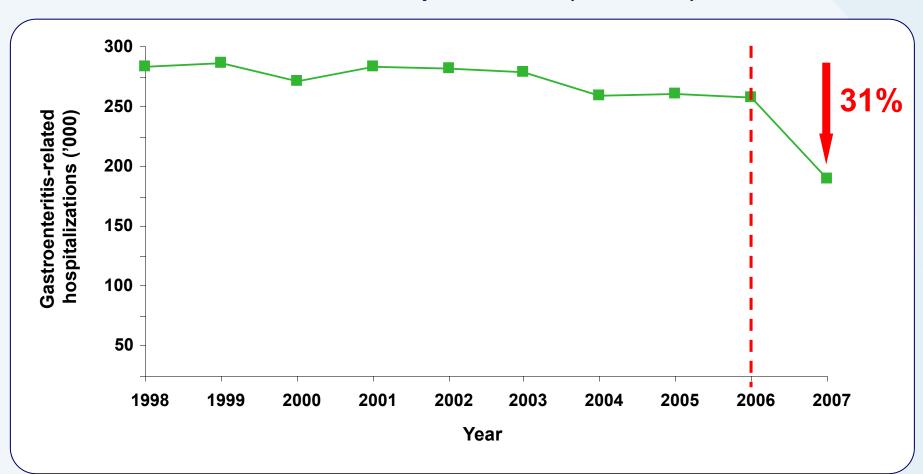


Immunisation against rotavirus gastroenteritis

Differentiate from *Rotateq*Only *Rotarix* completes the course at the earliest possible age

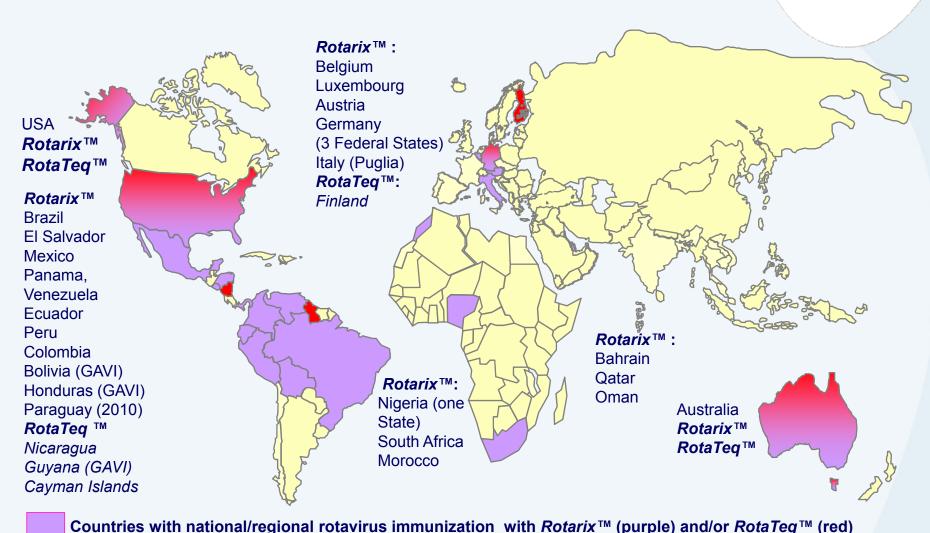
### Impact of rotavirus vaccination: Brazil

### **Gastroenteritis hospitalizations (1998-2007)**



# Rotarix: rotavirus UMV programmes





Countries without national rotavirus immunization

### Cervarix in 2010



Approved in 110 countries Including US and Japan (October 2009)

2009 sales £187 million (+38%) Q1 2010 sales £77 million (+60%)

Over half of competitive tenders won Over two-thirds by volume

WHO Prequalification (July 2009)
Global access to *Cervarix* via UNICEF & GAVI

# Cervarix: fulfilling the promise

Significant new data presented and published

Study-008

High efficacy against HPV-16/18 confirmed & significant protection beyond HPV-16/18

Study-010

**Superior immune profile** 

Study-007/023

Continued efficacy: 8.4 yrs so far

**All studies** 

Long-term safety

### Cervarix: the future



Current global HPV vaccine market currently approx. £1.3 billion

Significant potential in Japan, US & International First cervical cancer vaccine approved in Japan

Seeking improved European & International label

Globally only 5% of 12-18 year old girls currently vaccinated against HPV

Potential individual benefit for up to 99% of 18-25 year old women

### Synflorix: successful launch



Approved in 65 countries
Filed in 37 countries

Significant tender wins and market share gains
Q1 2010 sales £45 million

Long-term contract signed with Brazilian government €1.5 billion over 10 years

Advance Market Commitment (AMC) for pneumococcal vaccines launched (March 2010)
300 million doses of *Synflorix* over 10 years

AMC MARKET COMMITMENTS TO STATE OF THE PROPERTY OF THE PROPERT

WHO prequalification (October 2009)
Enables UN agency purchase

# Synflorix: future growth



Increasing market share range in key retail markets

Won over two-thirds of competitive tenders (by volume)

**Additional launches & new UMVs** 

Proven efficacy against acute otitis media (AOM)

### Boostrix: significant opportunity



- Despite effective childhood DTPa vaccination programmes, immunity wanes, and the number of cases is increasing
- dTpa and Td booster markets growing
  - Boostrix sales £139 million (+73%)
- Future dTpa market potential
  - Switch of adolescent booster programmes from dT to dTPa
  - Development of adult vaccination strategies (US, France & Germany)
  - Switch of adult Td boosters to dTpa

Growth rate is CER 19

### **GSK vaccines in 2010**

- A world leader in vaccines
- One of the broadest portfolios and fastest growing vaccines businesses in the world
- Unique expertise in adjuvant technology
- Strong pipeline including innovative therapeutic vaccine approaches
- Global footprint: ideally positioned to capture a significant market share in all territories

