

WHAT ARE VACCINES?

A vaccine is a preparation used to confer immunity against a disease by inoculation with dead or greatly weakened versions of disease-causing organisms or crucial fragments of the pathogens. If and when the immune system encounters 'real' disease it then itself prevents disease through reacting rapidly and effectively.

Immunisation and sanitation are the most effective ways to control and eradicate infectious disease. Since their introduction and widespread use in the twentieth century, vaccines have prevented more disease and more death than any other kind of medical treatment. And it is thanks to vaccines that deadly diseases such as smallpox, polio and diphtheria have for many people become distant memories.

THE HISTORY OF VACCINES

FIGHTING THE WORLD'S KILLER DISEASES

The science of medicine was revolutionised when Edward Jenner administered the first vaccination in 1796. He discovered that milkmaids infected with cowpox seldom contracted the severe and usually fatal human disease, smallpox. From that day on, vaccines changed the face of medicine and the burden of disease across the world.

However, it took another century before a new era of invention for vaccines was launched by great scientists such as Louis Pasteur. From these early days vaccines have become a central component of preventive medicine.

VICTORY OVER DISEASE

From the 1950s onwards, vaccination took on truly global dimensions. In 1956 the WHO selected smallpox for eradication from the world and, in 1958, it was the former Soviet Union that proposed an international campaign to eliminate the disease. Even at the height of the Cold War, there was universal support for this goal.

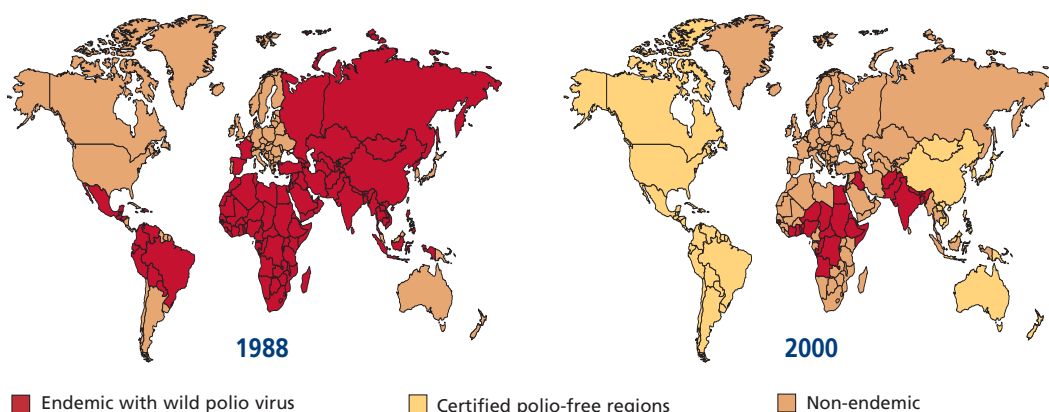
As a result of very high population coverage for smallpox inoculation,

and the worldwide campaign to eradicate the disease, the World Health Assembly in 1980 announced that the disease had been eradicated. It also recommended that vaccination against smallpox could cease. Jenner's late 18th century prediction of the eventual "annihilation of smallpox" had been achieved. However, today smallpox is back in the public eye because of its association with terrorist threats.

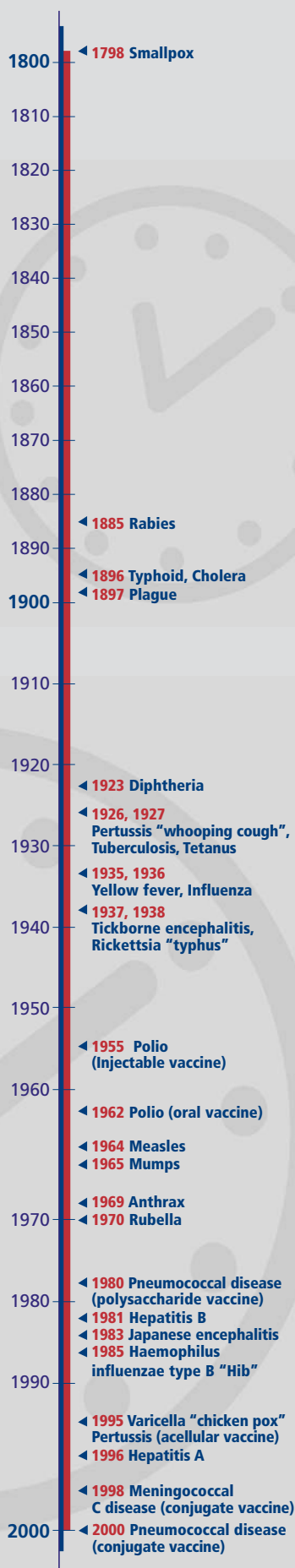
Even before the eradication of smallpox, governments around the world became committed to expanding immunisation. Many diseases such as diphtheria, tetanus, pertussis (whooping cough) and measles constituted a major cause of infant death. Almost every country in the world has introduced national immunisation programmes for these diseases.

In 1988 polio was targeted for global eradication and the world has since then been on track to be certified as polio-free by 2005. The WHO European Region was officially declared "polio-free" in July 2002.

Polio Eradication Progress 1988 - 2000



THE INTRODUCTION OF VACCINES



VACCINE DEVELOPMENT

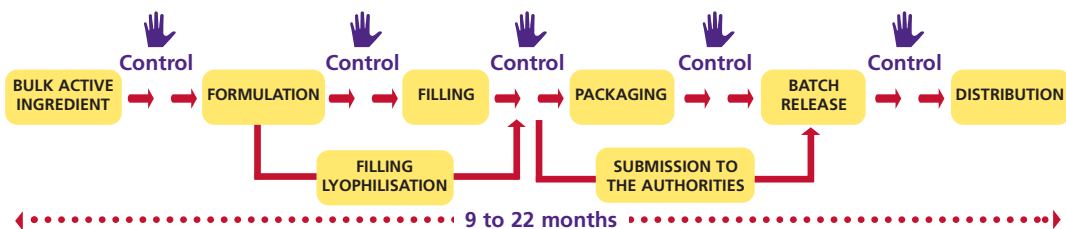
THE LONG ROAD FROM INITIAL IDEA TO PRODUCT LICENSE

Vaccine development is a complex and time-consuming process, and the time needed to develop a marketable product is almost invariably underestimated by many people who are not familiar with vaccine manufacturing. Before a vaccine is licensed and brought to market, it undergoes a long and rigorous process of research, followed by many years of testing. On average, the period for vaccine development is 12 years.

Despite long and expensive development periods, the successful conclusion of development of a new vaccine does not mean that the product automatically becomes a commercial success. Final approval for licensing and marketing of a vaccine requires that its quality, safety and efficacy have been demonstrated in well

designed and controlled studies. Long-term risk-conscious planning and courageous decision making, are therefore, a key part of good management in the vaccine business. And even then, the apparently minor technical detail of regulation can result in considerably longer development periods and higher costs.

Even after 12 years of research and development, the production cycle for a vaccine is long and complicated. Manufacturing of vaccines must be conducted in approved establishments, qualified and validated according to GMP (Good Manufacturing Practice) standards with an adequate infrastructure and separation of activities to avoid cross-contamination, as shown in the diagram below.



REGULATORY REQUIREMENTS FOR MARKET APPROVAL

Within the European Union, a new and comprehensive regulatory system for evaluation and authorisation of medicinal products was set up in 1995 to replace former regulatory procedures. EMEA (European Agency for Evaluation of Medicinal Products) represents the

main channel for new vaccine evaluation and licensing within Europe. EMEA's aim is to promote both public health and the free circulation of pharmaceuticals within Europe, providing benefits to users of new medicines, and to European pharmaceutical research.

TOMORROW'S VACCINES: PREVENTION AND THERAPY



Today, around 60% of the world's vaccines are manufactured in Europe. Europe plays a key role in research and development of preventive as well as therapeutic medicines. Some vaccines that

are in development target difficult to treat diseases, such as HIV/AIDS and malaria, as well as cancer, Alzheimer's disease, rheumatic disorders, and genital herpes, among others.

Europe has succeeded in controlling *Haemophilus influenzae* type b (Hib) and recently the outstanding impact of meningococcal C conjugate vaccines in the UK reflects the progress of vaccine research on a global scale. Finally, a totally new avenue being explored is therapeutic vaccines, to treat and prevent diseases, including some forms of cancer.

Today's vaccines are high quality biotechnology products which play a vital role in improving public health in Europe and around the world.

EVM member companies:

Aventis Pasteur | Aventis Pasteur MSD | Baxter | Berna Biotech | Chiron Vaccines | GlaxoSmithKline Biologicals PowderJect Pharmaceuticals | Solvay Pharmaceuticals | Wyeth Vaccines