European Vaccine Manufacturers

Scare stories versus Facts

A specialised group within EFPIA

VACCINES - A HIGHLY REGULATED SECTOR

The fundamental requirements necessary for a successful vaccine are its quality, safety and efficacy, and these must be clearly established by regulatory authorities before a vaccine is licensed. In addition, there is an ongoing process of post-marketing / post-licensing vaccine evaluation. These are little known among the general population.

Post-licensing evaluation of a vaccine's effectiveness in a vaccination programme is particularly important in determining its impact on the target disease, to identify possible changes in the vaccine's effectiveness in the field compared with a controlled study environment, and to detect possible adverse events not detected during clinical trials.
Clearly, the wider the vaccine coverage in a given population, the greater the chance that a rare condition may be reported by someone who was immunised during the same period. For this reason, post-marketing surveillance and regulation is not only essential and required by national authorities, but also contributes to ensuring the safety of vaccines.

MYTHS VERSUS FACTS

Myth

"Some people who get disease have been vaccinated, so vaccination will not be effective for my children or me."

Fact

If vaccines did not work, then we would see huge outbreaks of vaccine-preventable diseases in vaccinated populations. Nevertheless, not all people who are vaccinated develop protective immunity for reasons related to their individual immune response. About 1 in 10 people who are vaccinated do not have an immune system that responds to the vaccine due to factors such as age, chronic disease or malnutrition. However, the more people who are vaccinated in a population, the less chance that an unprotected person may encounter the pathogen (germ). Maintaining a high level of vaccine coverage is important due to a "herd effect" that slows down the circulation of a pathogen, reducing the chance of transmitting an infection.

Myth

"Public health improves because of better hygiene and sanitation, so vaccines are unnecessary."

Fact

Improved socio-economic conditions have undoubtedly had a direct impact on reducing communicable diseases, particularly the food-borne or water-borne infectious diseases. Nevertheless, the dramatically lower incidence of disease in many parts of the world over the years leaves little doubt about the additional beneficial impact of vaccines.

There are many examples, but one was the decision of the World Health Organization to declare the European Region polio free in June 2002.

Incidence of diphteria, tetanus, pertussis (whooping cough), and Hib meningitis in the United Kingdom prior to and following the introduction of vaccination

Diseases	year	Number of cases	Number of deaths
Diphteria	1939*	47,061	2,133
	1996	12	0
Tetanus	1960*	NA***	32
	1996	8	0
Pertussis	1956*	94,410	92
	1996	2,387	2
Hib meningitis**	1991*	92	22
	1996	2	0

Sources: Office for National Statistics, public Health Laboratory Service

*Last year before vaccination
** *Haemophilus influenzae* type b menengitis
*** Not a notifiable disease until 1968

EVALUATING WEBSITE INFORMATION - GUIDELINES TO PARENTS*

The internet is flooded with information on immunisation, vaccines and diseases.
The challenge is to know which of these sources are accurate and reliable, rather than being based on non-scientific rumours and scare stories.

There are a few basic guidelines, which can help parents and the public in evaluating the credibility of the information they find on the internet:

- Consider the source. Who is responsible, and can the information provider or webmaster be contacted?
- Ask the following questions: Is the medical information reviewed by scientific experts? Is the information updated? What is the scientific evidence for claims made, and is the original source of the facts referenced?
- Establish the purpose of the website. Is the purpose to provide accurate information about the topic, or does it promote a health care product?
- And finally, verify the information found on the internet with a doctor.

*Source: **National Network for Immunization Information**
www.immunizationinfo.org/parents/evaluatingWeb.cfm

Myth
"Vaccines cause many harmful side effects, illnesses, and even death — not to mention possible long-term effects we don't even know about."

Fact
Vaccines are rigorously tested for their safety and effectiveness, and side effects continue to be monitored through post-marketing surveillance systems long after vaccines have been licensed and marketed. Although vaccines have a small risk of side effects, such as redness and possible soreness at the vaccination site, or brief fever, these risks are less important than those of the disease itself.

Myth
"Vaccine-preventable diseases have been virtually eliminated from my country, so there is no need for my child to be vaccinated."

Fact
It's true that vaccination has enabled us to reduce most vaccine-preventable diseases to very low levels in many countries. However, some diseases are still quite prevalent — even epidemic — in other parts of the world. Travellers can unknowingly be carriers of viruses or bacteria that could quickly spread throughout the population, causing epidemics. Furthermore, low vaccine coverage leads to outbreaks of diseases.

A clear example of this can be seen in the case of Ireland, where the re-emergence of measles has increased significantly, with a total of 234 cases since late November 2002. There has been a substantial decline in MMR vaccine uptake, with coverage falling to 73% of the population, which is well below the WHO recommendations. The most likely cause of this decrease can be attributed to the adverse publicity surrounding the vaccine.

Myth
"Giving a child multiple vaccinations for different diseases at the same time increases the risk of harmful side effects and can overload the immune system."

Fact
A number of studies have been conducted to examine the effects of giving various combinations of vaccines simultaneously. These studies have shown that the recommended vaccines are as effective in combination as they are individually, and that such combinations carry no greater risk for adverse side effects. In one recent study it was estimated that even if 11 vaccines were given to infants all at one time, only about 0.1% of the child's immune system[1] would be "called into action" by the vaccine. Furthermore, vaccines never "use up" even a tiny fraction of the immune system since the child's B and T cells are constantly being replenished.

In fact, vaccines strengthen the body's immune system by engaging protective immune responses against a number of viruses and bacteria. Infection with certain viruses (such as wildpolio virus) or bacteria (such as those that cause pneumonia) can weaken a child's immune system, leaving the child more susceptible to a secondary infection. For example, a child infected with the measles virus is likely to develop middle ear infections or pneumonia if exposed to these bacteria. On the other hand, a child who has been vaccinated against measles develops immunity against measles and its potential complications.

[1] Reference: Offit PA, Quarles J, Gerber MA et al. Addressing parents' concerns : do multiple vaccines overwhelm or weaken the infant's immune system? Pediatrics 2002;109(1):124-129.

EVM member companies:
Aventis Pasteur | Aventis Pasteur MSD | Baxter | Berna Biotech | Chiron Vaccines | GlaxoSmithKline Biologicals
PowderJect Pharmaceuticals | Solvay Pharmaceuticals | Wyeth Vaccines