

# Vaccine safety

## Key questions answered



### What is in a vaccine?

Many vaccines contain an antigen, which is a weakened or inactivated form or component of a virus or bacterium. When a person is vaccinated, their immune system recognises the antigen as foreign, and creates cells called antibodies which fight the virus or bacterium.

### How do I know that vaccines are safe?

Vaccine safety is ensured by a strict process of testing, evaluation and regulation. All vaccines must go through several stages before being approved for use in the EU:

- › **Rigorous testing** by its developer. After testing, the vaccine developer submits the results to the European Medicines Agency (EMA).
- › **Scientific evaluation** by regulatory authorities. Vaccines are only approved if evaluations show that the vaccine's benefits are greater than its risks.
- › **Regulation in individual countries.** Companies are required to conduct stringent testing on each batch of vaccine released onto the EU market. National authorities decide the related acceptance criteria.

### How are vaccines tested in humans?

**After laboratory studies, the vaccines can be tested on people in clinical trials.**

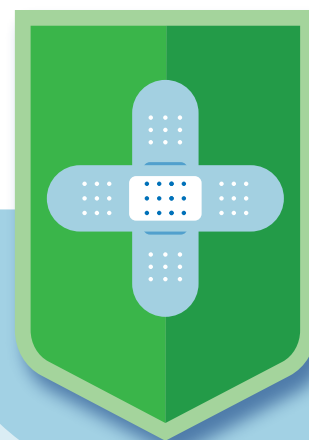
These begin with a small group of volunteers to check that it can be used safely. Then in consecutive phases they are expanded to larger groups of volunteers to make sure that the vaccine is optimised in terms of safety and effectiveness.

Authorities oversee all the trials to check that everything is being done correctly.

### Are there other ingredients?

In addition to one or more antigens, other components can also be added to help keep the vaccine stable and effective. These include:

- › **Stabilisers:** components that keep the vaccine stable.
- › **Adjuvants:** substances that strengthen the immune response, leading to protection that is stronger, faster and longer lasting.
- › **Excipients:** inactive ingredients, like water, salts, stabilisers and preservatives that improve vaccine quality and make it easier to inject the right dose.
- › **Other (trace) substances:** compounds that are used in the manufacturing process. These may be present in some vaccines, in very small amounts. When such compounds may cause a reaction in sensitive or allergic individuals (such as ovalbumin, a protein found in eggs), their presence is declared in the vaccine information given to healthcare workers and people getting a vaccine, so they know to carefully look for possible reactions.



### What are the different types of vaccine?

**Whole organisms:**

- › **Inactivated vaccines** contain viruses that have been inactivated (killed) in a lab using heat or chemicals.
- › **Live attenuated vaccines** contain live viruses or bacteria that have been weakened by changing their DNA or by selecting the weakest viruses or bacteria to include in the vaccine.

**Parts of organisms,** which can be given directly (recombinant) or made in the body by vaccinating with mRNA or viral vectors that contain instructions.

**Toxoid,** which do not protect against the organism but against the toxins produced by them.



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