

## Profile of the Paul-Ehrlich-Institut

The Paul-Ehrlich-Institut (PEI) is the Federal Institute for Vaccines and Biomedicines. As a federal regulatory authority active in the field of pharmaceuticals, its work is in the service of public health.

The PEI examines and evaluates the benefits and risks of human biomedical and immunological veterinary medicinal products as part of clinical development, marketing authorisation and post-marketing follow-up.

Indispensable for the tasks of the PEI is its own experimental research. The PEI reports to the Federal Ministry of Health.

The institute employs around 900 people at its location in Langen.

[www.pei.de/institut](http://www.pei.de/institut)

## Medicinal Products in the Responsibility of the PEI

The PEI tests and assesses the following medicines for human use:

- vaccines for the protection against infectious diseases
- antibodies and immunoglobulins (sera) e.g. for the treatment of cancer, rheumatism, and autoimmune diseases as well as neurological diseases
- allergens for allergy diagnostics and therapy
- advanced therapy medicinal products (ATMPs) such as gene therapeutics, somatic cell therapies, tissue engineered products (TEPs) and xenogenic drugs
- blood products and stem cell preparations
- tissue preparations.

The PEI also tests and evaluates immunological veterinary medicinal products:

- vaccines
- other immunological veterinary medicines, e.g. immune-modulators, sera for veterinary use

[www.pei.de/arzneimittel](http://www.pei.de/arzneimittel)

## Tasks

Key tasks of the PEI include:

- the marketing authorisation of vaccines and biomedicines
- the authorisation of clinical trials
- official independent experimental batch testing and batch release, independently from the manufacturer
- scientific advice prior to applications for marketing authorisation applications or applications for the authorisation of clinical trials
- the detection and evaluation of adverse reactions (pharmacovigilance)

- the implementation and coordination of necessary measures to prevent risks to human and animal health
- testing-related, basic and applied research

The PEI reviews and evaluates vaccines and biomedicines with the aim of ensuring a positive benefit-risk balance of these medicines, which are available on the German and European markets. This examination is not based solely on documents, but the PEI also carries out its own experimental tests - in particular in the context of official batch release - or performs inspections with the license holders.

[www.pei.de/aufgaben](http://www.pei.de/aufgaben)

## PEI International

Authorisation and trade in medicines for the European market are standardised and fully regulated by European legislation. This results in numerous other tasks for the institute. The PEI assumes advisory functions for the federal and state governments. It is internationally active in numerous committees and projects such as the World Health Organization (WHO), the European Medicines Agency (EMA), the European Commission (EC) and others.

[www.pei.de/international](http://www.pei.de/international)

## WHO Collaborating Centers

PEI has two WHO collaborating centers, focusing on vaccines as well as on blood products including in vitro diagnostics.

[www.pei.de/who-kooperationszentren](http://www.pei.de/who-kooperationszentren)

## Research

The PEI receives international recognition for its combination of medicine testing, regulatory research and basic research.

High-level basic research leads to a better understanding of mechanisms of action and initiates novel biomedical treatment approaches.

The scientists at the PEI are developing new methods and important standards for the testing of vaccines and biomedicines. In addition, they investigate the causes of unexpected side effects and thus contribute significantly to preventing them in the future.

The institute has defined three cross-departmental research priorities:

- regulatory research & innovative product testing
- interactions of pathogen & host or biomedicine & organism
- experimental vaccines, therapies & diagnostics.

[www.pei.de/forschung](http://www.pei.de/forschung)