In Germany *in-vitro* diagnostics, which have been produced either biotechnologically or by use of pathogens and which are destined for the prevention, diagnosis or treatment of animal diseases, generally may only be placed on the market or administered after an official marketing authorisation has been granted.

The competent authority for granting marketing authorisations (licensing authority) for veterinary *in-vitro* diagnostics is the Friedrich-Loeffler-Institut (FLI), Federal Research Institute for Animal Health.

The procedure is initiated after submission of an application by the pharmaceutical entrepreneur. This is the person who places the product on the market under his own name (manufacturer, distributor). To this end, he must have his registered place of business in a member state of the EU or in a contracting state of the Agreement on the European Economic Area. The experimental testing required for a decision on the marketing authorisation will be done in the respective test laboratory of the FLI, which is in most cases a reference laboratory for the disease in question.

After the marketing authorisation has been granted, each batch of a product must be tested and can only be marketed or applied after release by the competent licensing authority. The marketing authorisation holder is obliged to inform the competent licensing authority of new facts without delay and to submit the respective data and documentation.