Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

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Information for Doctors

ALLERGEN-SPECIFIC IMMUNOTHERAPEUTIC AGENTS UNDER THE TRANSITIONAL REGULATIONS OF THE THERAPY ALLERGEN ORDINANCE

Current Product Development Status

The German Therapy Allergen Ordinance (Therapieallergene-Verordnung, TAV), which came into force in 2008, aims to convert allergen-specific immunotherapy (AIT) products, which were sold as individual formulations and as active ingredient extracts from common allergen sources in Germany – sweet grasses (not including maize), birch, alder, hazel, dust mites, bee and/or wasp venom – into tested and authorised products. This conversion requires proving the quality, efficacy, and safety of each AIT product and an authorisation procedure assessment. So far, the TAV in Germany has led to a reduction of the number of individual formulations used for common allergy treatments from 6,654 (in particular mixtures of questionable composition) to currently 43 products (with predominantly one allergen or allergens from a homologous group) and stimulated the collection of clinical data in accordance with the current state of science. This has launched a new generation of tested medicines for allergy treatment.

At the time of the entry into force of the TAV, 6,654 individual formulations containing one or more of the allergen sources listed above were on the market in Germany. If a pharmaceutical company was still seeking authorisation for a product at that point, an authorisation dossier had to be submitted to the Paul-Ehrlich-Institut by 1 December 2010. This was the case for 123 products. Pursuant to section 3 subsection 1 of the TAV, the products can stay on the market, subject to federal batch testing, without authorisation until the decision on authorisation was issued. The transitional regulations of the TAV provide a period of one year for these products to remedy any deficiencies in the submitted authorisation documents. This period may be extended by a maximum of 7 years for the submission of clinical data if necessary to remedy inadequate clinical data due to the nature of therapeutic allergens. For the remaining 6,531 products for which no authorisation application was submitted, marketability ended on 14 November 2011.

In Germany alone, 59 applications to conduct clinical studies on TAV products were submitted to the Paul-Ehrlich-Institut, 45 of which were approved. Two AIT products, which were further developed in the development program under the transitional

regulations of the TAV, received regulatory authorisation in 2018. A further 43 of the initial 123 applications for authorisation are currently active under the TAV. With regard to the submission of clinical data, initial deadlines for the submission of data from dose determination studies were initially approved and, after submission of the data, a decision was made as to whether a further extension of the deadline would be issued. The last product-specific deadlines pursuant to the TAV approved under the transitional regulations will end in 2026. If the clinical deficiencies are not rectified by the set deadline, the authorisation will be denied by the Paul-Ehrlich-Institut as the higher federal authority responsible in Germany and the AIT product must be taken off the market. If study results that do not support sufficient efficacy and safety emerge, the Paul-Ehrlich-Institut will no longer grant batch release in the ongoing TAV process. This means that the corresponding products can be further developed under the TAV, but no new batches will enter the market. This measure has already been taken for several AIT products.

Contact

Email: allergologie@pei.de