Scientific summary

CHALLENGES IN THE IMPLEMENTATION OF EAACI GUIDELINES ON ALLERGEN IMMUNOTHERAPY: A GLOBAL PERSPECTIVE ON THE REGULATION OF ALLERGEN PRODUCTS

Regulatory approaches for allergen immunotherapy (AIT) products and the availability of high quality AIT products are inherently linked to each other. While allergen products are available in many countries across the globe, their regulation is very heterogeneous. First, we describe the regulatory systems applicable for AIT products in the European Union (EU) and in the United States (US). For Europe, a depiction of the different types of relevant procedures, as well as the committees involved is provided and the fundamental role of national agencies of the EU member states in this complex and unique network is highlighted. Furthermore, the regulatory agencies from Australia, Canada, Japan, Russia, and Switzerland provided information on the system implemented in their countries for the regulation of allergen products. While AIT products are commonly classified as biological medicinal products, they are made available by varying types of procedures, most commonly by either obtaining a marketing authorisation or by being distributed as named patient products. Exemptions from marketing authorisations in exceptional cases, as well as import of allergen products from other countries, are additional tools applied by countries to ensure availability of needed AIT products. Several challenges for AIT products are apparent from this analysis and will require further consideration.

Published as: Bonertz A, Roberts G, Hoefnagel M, Timon M, Slater JE, Rabin RL, Bridgewater J, Pini C, Pfaar O, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Sheikh A, Pawankar R, Hamerlijnk D, Klimek L, Agache I, Angier E, Casale T, Fernandez-Rivas M, Halken S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, Gerth van Wijk R, Bonini S, Muraro A, Vieths S. Challenges in the implementation of EAACI guidelines on allergen immunotherapy: A global perspective on the regulation of allergen products. Allergy 2017 Aug 3. doi: 10.1111/all.13266. [Epub ahead of print]