

PROVIDER PROFILE

Name of the organisation	Finnish Medicines Agency (FIMEA)
Type of the organisation	National Competent Authority
Contact email(s)	innovation.office@fimea.fi
Offering website	https://www.fimea.fi/web/en/marketing_authorisations/innovation_office
Service language(s)	Finnish, English
Target group	Academic Principal Investigators/Groups/Consortia, SMEs, Big Pharma
Short support description	<p>We provide two platforms for basic guidance on regulatory and scientific issues related to medicinal products. Our goal is to provide easier access to the regulatory and scientific expertise of FIMEA. Informal regulatory guidance is a platform for change of views between authorities and drug developers and innovators who are not yet fully aware of the regulatory requirements or guidelines. Innovators at an early stage of drug development may benefit from this kind of discussions which are provided free of charge. The goal for the informal regulatory guidance process is also to establish contacts and networking with the other European innovation offices of national competent authorities (EU Innovation Network) and local stakeholders, including public investors. Formal scientific advice is primarily meant for more advanced drug development programs. It answers the targeted questions on study design and questions for which the regulatory guidelines are not yet available. It can also assist in cases where the developer wants to diverge from the established guidelines. FIMEA answers questions regarding development of medical products based on the applicant's documentation. Advice may be requested for all medicinal products, irrespective of subsequent choice of procedure for approval.</p>

This profile is part of the [Comprehensive Inventory \(CI\)](#) provided by the [STARS project](#).

Purpose of the CI is to assist European academic drug developers in finding support on regulatory affairs. The inventory lists various support services provided by national competent authorities, public actors and private entities.

For information about the STARS project please visit www.csa-stars.eu or contact CoordinationSTARS@bfarm.de.