Chief Pharmaceutical Inspectorate

Supervision of manufacturing and import of medicinal products

Pursuant to the Pharmaceutical Law Act, activities of manufacture or import of medicinal products or investigational medicinal products require an authorisation. The Chief Pharmaceutical Inspector issues such authorisations in accordance with the act.

The manufacture of advanced therapy medicinal products hospital exemption (ATMPs-HE) requires an authorisation of the Chief Pharmaceutical Inspector. Such authorizations are issued by way of a decision.

Pursuant to the Pharmaceutical Law Act, at least once every three years, GMP Inspectors conduct planned inspections intended to check whether Good Manufacturing Practice requirements are being met. In the case of a justified suspicion that there are any deficiencies posing a risk to the quality, safety or efficacy of medicinal products, or quality or safety of active pharmaceutical ingredients, the Chief Pharmaceutical Inspector orders an ad-hoc inspection.

Moreover, if a Marketing Authorisation Holder applies for an authorisation or a medicinal product is imported to the Republic of Poland for further processing, the Chief Pharmaceutical Inspector issues opinions on the compliance of the manufacturing conditions with the requirements of the Good Manufacturing Practice at manufacturing sites in third countries. Before an opinion is issued, an inspection must be carried out by GMP Inspectors.

GMP Inspectors supervise the protection and disposal of narcotics, psychotropic substances and precursors of category 1 provided for in the Act on Prevention of Drug Abuse and related regulations