

Chief Pharmaceutical Inspectorate

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Chief Pharmaceutical Inspector

- as a central governmental administration authority, Chief Pharmaceutical Inspector manages State Pharmaceutical Inspection with the assistance of Chief Pharmaceutical Inspectorate,
- Chief Pharmaceutical Inspector is appointed and dismissed by the Prime Minister at a request of the Minister of Health,
- is the appeal body for matters related to the execution of tasks and competences of the Pharmaceutical Inspection (the second instance authority with respect to decisions made by voivodship pharmaceutical inspectors),
- the first instance authority in relation to matters specified in the Pharmaceutical Law.

The most important tasks of the Chief Pharmaceutical Inspector:

- prioritizing the activities of the Pharmaceutical Inspection,
- supervising the conditions of manufacturing and importing of medicinal products for human and veterinary use, cooperating with relevant Pharmaceutical Inspections in third countries, including EU Member States,
- ensuring that GMP and wholesale distribution inspections are conducted in accordance with unified standard inspection procedures,
- supervising compliance of the advertising of medicinal products with the provisions of Pharmaceutical Law,
- issuing decisions related to:
 - suspending or recalling medicinal products, or withdrawing them from the market,
 - withholding the trade in medical devices in pharmaceutical wholesale stores, pharmacies, pharmacy outlets, points of out-of-pharmacy sale referred to in Article 71, sec. 1, item 1-4 or banning the use of medical devices in healthcare centres, if there is a suspicion that a given product or device does not meet the quality requirements established for it,
 - granting, amending, withdrawing or refusing to grant a manufacturing authorisation for medicinal products and an authorisation for wholesale trade in medicinal products and medical devices,
- issuing the following authorisations:
 - authorisations for manufacturing, processing or altering of intoxicants or psychotropic substances,
 - authorisations for manufacturing, processing or altering of precursors of category 1,
 - authorisations for collecting poppy milk, opium from poppies and cannabis and cannabis resin allowed for scientific research purposes only,
 - authorisations for wholesale trade in intoxicants or psychotropic substances and authorisations for wholesale trade in precursors of category 1,
- issuing authorisations for import, export, intra-community delivery or intra-community purchase of

intoxicants or psychotropic substances, and licenses for import and export of precursors of category 1,

- supervising the manufacturing, processing, alteration, storage, trade and disposal of intoxicants, psychotropic substances and precursors of category 1 by checking whether the obligations referred to in Regulation 273/2004, Regulation 111/2005 and the Act on Prevention of Drug Abuse are fulfilled by entrepreneurs referred to in Article 35 sec. 1 of the act referred to above.