Chief Pharmaceutical Inspectorate

Supevision of Active Pharmaceutical Ingredients

Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards prevention of the entry into legal supply chain of falsified medicinal products introduces new requirements for the manufacturers, importers and distributors of active pharmaceutical ingredients. According to the requirements listed therein, competent authorities are obliged to maintain a register of manufacturers, importers and distributors of active pharmaceutical ingredients and verify whether they meet the GMP/GDP requirements by conducting regular inspections.

The Main Pharmaceutical Inspector performs activities intended to develop the register required by the regulation mentioned above. Therefore, the Chief Pharmaceutical Inspector accepts and analyses applications submitted by entrepreneurs related to an entry to the register. If it is decided that an inspection must be conducted, GMP Inspectors carry out the inspection to check whether the entrepreneur follows the GMP and GDP requirements in the scope of manufacture, import and distribution of active pharmaceutical ingredients.