

The Office

Opublikowany na Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (<https://archiwum.urpl.gov.pl>)

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In accordance with the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws 2011, No 82, item 451, as amended), the statutory activities of the Office include three core areas:

– carrying out procedures and activities involving medicinal products for human use and veterinary medicinal products, in particular:

- granting, by means of decisions, marketing authorisations for medicinal products;
- providing information on documents and actions required in the medicinal product authorisation process;
- granting, by means of decisions, parallel import licences for medicinal products;
- keeping the Official Register of Medicinal Products Authorised in the territory of the Republic of Poland and issuing decisions refusing access to this register;
- granting, by means of decisions, authorisations of clinical trials or veterinary clinical trials;
- keeping the Central Register of Clinical Trials;
- conducting Clinical Trial Inspections, including the verification of compliance of clinical trials of medicinal products or investigational medicinal products with the requirements of the Good Clinical Practice, and in the case of clinical trials of veterinary medicinal products or investigational veterinary medicinal products – with the requirements of the Veterinary Good Clinical Practice;
- collecting reports and information on adverse reactions to medicinal products, investigational medicinal products, veterinary medicinal products and investigational veterinary medicinal products;
- pharmacovigilance and safety monitoring of medicinal products and veterinary medicinal products;
- carrying out inspections of the pharmacovigilance system for medicinal products;
- at least once a year, publishing the Official List of Medicinal Products Authorised in the territory of the Republic of Poland in the Official Journal of the minister competent for health, with a separate list of veterinary medicinal products;
- publishing a list of medicinal products authorised by the President of the Office in the Public Information Bulletin on a monthly basis,
- keeping a record of manufacturers of active substances used in the manufacture of veterinary medicinal products with anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties;

– carrying out procedures and activities involving the safety, marketing and use of medical devices, in particular:

- issuing decisions in respect of medical devices;
- keeping a database of reports and notifications concerning medical devices;
- supervising medical incidents and measures in the area of safety of medical devices;
- adopting decisions granting permissions for clinical trials for medical devices or active implantable medical devices and for modifications of clinical trials;
- listing clinical trials of medical devices in the Central Register of Clinical Trials;
- control of clinical trials involving medical devices;
- surveillance of medical devices manufactured or marketed and released for use in the territory of the Republic of Poland;
- resolution of disputes involving classification rules and establishing the following:

– the classification of medical devices,

– the classification of medical device accessories,

– the qualification of in-vitro diagnostic medical devices;

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- issuing Certificates of Free Sale;
- cooperation and information exchange with international organisations, including exchange of safety information;

– carrying out procedures and activities involving biocidal products, in particular:

- granting authorisations for making available on the market and use of biocidal products;
- granting parallel trade authorisations by means of decisions;
- granting marketing authorisations for biocidal products by means of decisions;
- keeping the List of Biocidal Products;
- evaluating dossiers for active substance approvals;
- keeping a register of scientific research and development activities aimed at placing on the market of biocidal products or active substances intended for exclusive use in a biocidal product;
- keeping a record of reports on poisonings arising from biocidal products;
- providing information on documents and actions required in the authorisation process for biocidal products;
- publishing the Official List of Biocidal Products Authorised in the territory of the Republic of Poland in the Official Journal of the minister competent for health matters;
- publishing a list of biocidal products authorised in the territory of the Republic of Poland in the Public Information Bulletin, on a monthly basis.

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