

Legal Alert

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MEDICINAL PRODUCTS, MEDICAL DEVICES, BIOCIDAL PRODUCTS IN THE CONTEXT OF THE COVID-19 EPIDEMIC



RESTRICTIONS ON TRADE

- **Adding more products to the anti-export list (the requirement to report export to the Chief Pharmaceutical Inspectorate (GIF) 30 days prior to the planned export or sale outside of Poland);** the list includes inter alia: popular anti-inflammatory and analgesic products available over the counter, medical caps, surgical gowns, fleece aprons, surgical masks, oxygen masks, medical shoe covers, operating room garments, surgical gloves, treatment gloves, electronic thermometers (list dated 17.03.2020).
- **The obligation to notify (not later than 36 hours in advance) the voivod competent for the locality of the intention to export or sell** the following products outside of the territory of Poland: safety goggles, TYVEK type suits, FFP2/FFP3 masks, surgical masks, shoe (footwear) covers, latex gloves, nitrile gloves, disinfectants for hands, surfaces and spaces (as at 25.03.2020).
- **Ban on exports or sale outside of Poland of ventilators and patient monitors.**



SIMPLIFIED PROCEDURE FOR REGISTRATION OF BIOCIDAL PRODUCTS

- **Derogation from the registration requirements for biocidal products used for disinfection:** it is possible to issue – **for no more than 180 days** – a permission to place on the market or use a biocidal product which does not meet the specific requirements for the issuance of a permission in line with a “standard” procedure.



PERSONAL PROTECTIVE EQUIPMENT AND MEDICAL DEVICES WITHOUT THE CE MARK

- **The Minister of Health has issued an authorization to purchase specific personal protective equipment before completion of its compliance evaluation and without placing the CE mark** - for use by medical personnel to prevent the spreading of the SARS-CoV-2 virus. The authorization shall remain in force for no longer than 30 days after lifting the state of epidemic threat.
- **It is possible to buy and use personal protective equipment and medical devices if they are admitted to trade in states other than the EU member states and the European Free Trade Association (EFTA) member states** – parties to the European Economic Area agreement.



SPECIAL POWERS GRANTED TO AUTHORITIES

- **Seizure for the State Treasury of:** medicinal products, foodstuffs for particular nutritional use, medical devices or personal protective equipment required for patients – to replenish the strategic reserve – by a decision of the Minister of Health
- **Giving instructions related to counteracting COVID-19:**
 - **to state and self-government entities** – for the voivod competent for the locality, and
 - **to business undertakings** – for the President of the Council of Ministers
- **Ban on export or sale outside of the territory of Poland of specific products** – in consequence of a request made by a voivod to the President of the Council of Ministers (in connection with notification by business undertakings of the intention to export or sell).
- **Imposition of the distribution obligation:**
 - of medicinal products, foodstuffs for particular nutritional use or medical devices – **on pharmaceutical wholesalers,**
 - of personal protective equipment – **on producers, distributors or importers,**
 by a decision of the Chief Sanitary Inspector.
- **Determination of maximum prices on medicinal products** (both prescription and over the counter) medical devices, foodstuffs for particular nutritional use, which may be used for counteracting COVID-19 – by an announcement of the Minister of Health.
- **Imposition on new entities of the reporting obligation to the Integrated System of Monitoring Trade in Medicinal Products (ZSMOPL)** – by a regulation of the Minister of Health.

Contact us



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