

Legal Alert

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ANTI-CRISIS SHIELD regulatory changes

DISTRIBUTION

- **Possible 'faster' export/sale of products included on the list of products facing potential shortages in Poland.** The Main Pharmaceutical Inspectorate (GIF) will be able to provide information about the lack of objection and the entrepreneur will be able to export/dispose of products immediately upon the receipt of such information.
- **Possibility to impose the obligation to submit reports to the Integrated Monitoring System for Medicinal Products (ZSMOPL)** on every entity involved in the production and wholesale of medical devices, foodstuffs for particular nutritional uses and biocidal products (connection within 24 hours of the imposition of the obligation with possible extension).
- **Possibility to impose the obligation to distribute:**
 - ✓ medicinal products, foodstuffs for particular nutritional uses or medical devices,
 - ✓ personal protective equipment,
 - ✓ biocidal products.
- **Disposal to Polish wholesalers – extension of the scope of obliged entities.** This obligation may apply to all entities involved in the production or wholesale distribution of medical devices and to producers and importers of foodstuffs for particular nutritional uses.

PHARMACIES

- **No obligation for a pharmacy manager to be present at pharmacy premises during its working hours** – the presence of a pharmacist is sufficient.
- **Pharmacists may prescribe medicines where a threat to patient's health is identified** – the patient's condition does not have to be urgent.
- **Limit of medicines per patient.** Possible limitation of the quantity of medicinal products, medical devices, foodstuffs for particular nutritional uses and biocidal products per one patient during a given period of time. On 1st April, 2020, the Minister of Health already announced a list on the limitation of the quantity of medicinal products per one patient (*Arechin* and *Plaquenil*).

REIMBURSEMENT

- **Extension of reimbursement decisions which validity ends before 1 July 2020 and the lists of reimbursed products until 31 August 2020** – the list of reimbursed products for March is binding until the end of August.
- **The suspension of running of the time period for reimbursement proceedings by virtue of law until 31 August 2020.**
- **Reimbursement decisions that were to become effective on 1 May 2020 shall be postponed until 1 September 2020.**

OTHER

- **Possibility to set maximum prices and margins** under the terms of the Reimbursement Act for medicinal products, medical devices, foodstuffs for special nutritional purposes, biocidal products and pharmaceutical materials which may be used in connection with COVID-19 combating.



Contact us

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