

Export or sale outside the Republic of Poland

Pursuant to Article 37av of the Pharmaceutical Law Act (Journal of Laws 2019.499, as amended), a business entity is required to report to the Chief Pharmaceutical Inspector the intent to export outside the Republic of Poland or to sell to an entity running a business outside the Republic of Poland, or the fact of having exported or sold, medicinal products, foodstuff for particular nutritional uses, and medical devices listed in the Announcement of the Minister of Health constituting a list of products facing potential shortages within the Republic of Poland, referred to in Article 37av(14) of the Pharmaceutical Law Act.

I. Reporting the intent to export or sell products outside the Republic of Poland

The form of the report of the intent to export or sell outside the Republic of Poland needs to be filled in and, after printing and signing it, delivered to the Chief Pharmaceutical Inspectorate in accordance with the Administrative Procedure Code. A separate form must be filled in for each product.

Within 30 days of receiving the report of the intent to export or sell outside the Republic of Poland products facing potential shortages, the Chief Pharmaceutical Inspector may decide to object to the intent to export or sell. The objecting decision of the Chief Pharmaceutical Inspector needs to be published in the Public Information Bulletin of the Chief Pharmaceutical Inspector.

Pursuant to Article 37av(4 and 5), as of the objection publication in the Public Information Bulletin, the decision to object is deemed duly served. The decision to object is made immediately enforceable.

- The objection of the Chief Pharmaceutical Inspector obligates the business entity to sell the medicinal products, foodstuff for particular nutritional uses, and medical devices within the Republic of Poland only, in amounts specified in the objection, in order to provide health care services in the country.

II. Reporting the fact of having exported or sold products outside the Republic of Poland

If the Chief Pharmaceutical Inspector does not issue the decision to object to the reported intent within 30 days of receiving the report, it means that the medicinal product, foodstuff for particular nutritional uses, or medical device specified in the report can be exported or sold outside the Republic of Poland.

The business entity is required to notify the Chief Pharmaceutical Inspector of the fact of exporting or selling within 7 days from the export or sale outside the Republic of Poland.

- In order to fulfil the reporting obligation, a filled-in and signed report form needs to be delivered to the authority as per the Administrative Procedure Code.

III. List

The current Announcement of the Minister of Health on a list of medicinal products, foodstuffs for particular nutritional uses, and medical devices facing potential shortages within the Republic of Poland is provided in the [Official Journal of the Minister of Health](#).

Source: www.gov.pl