

PHARMACY SELECTION OF THE EDITOR-IN-CHIEF

Who re-exports drugs from the Czech Republic? SÚKL publishes data that give an almost complete answer. The Constitution imposed a new legal obligation on it

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Opinions differ on the effect of re-exports on the availability of medicinal products for Czech patients. It is definitely not widespread or fatal. However, it may concern specific medicines and therefore specific patient groups. Photo: Pixabay

From 1 January this year, the State Institute for Drug Control (SÚKL) is obliged to publish detailed data on so-called re-exports, including the identification of distribution companies that participate in them. It is now possible to find a monthly report on the SÚKL website with a list of medicinal products that are subject to a medical prescription and have been exported from the Czech Republic abroad. The number of packages, the price of the originator and the name and ID number of the exporter are stated. Instead of the current unverified information or anonymized data, it is now publicly known who exports the most medicines originally intended for Czech patients. Overall, one large distributor dominates, followed by a group of small companies that specialize in re-exports. In March, however, these small exporters broke into the top positions.

A new obligation of SÚKL was imposed by the amendment to Act No. 378/2007 Coll., On Medicinal Products, which was approved by the Parliament in the autumn of last year. The general public noticed the amendments mainly due to the regulation of medical cannabis, however, it also contains provisions in § 99, para. e), which states that SÚKL publishes on its website: “*summary data on medicinal products dispensed only on prescription distributed outside the market in the Czech*

Republic, processed from data reported in accordance with § 77 par. f) on medicinal products distributed by the distributor to other persons for distribution or dispensation outside the Czech Republic, indicating the distributor's identification, identification of the distributed medicinal product by the code assigned by the Institute, name and number, number of packages, originator's price and It is interesting that a similar provision concerning the movement of goods within the Czech Republic precludes the identification of a distributor (Section 99 (2) (d)).

Replacement at number one

Currently, three monthly reports are published on the website - for January, February and March of this year (in the report on the supply of distributed medicinal products for human use under the instruction DIS-13 - abroad).

According to these data, the largest re-exporter is the wholesale distribution company Alliance Healthcare, which exported almost 125 million crowns in the first three months. This is followed by companies that do not supply drugs to Czech patients and the main source of their business is re-exports - Leram (103 million crowns in three months), Jihlavská lékárnická (47 million), Pharmawell (43 million), DerStar Pharma CZ (42 million) and Arex Pharma (41 million).

However, the total volume of exports gradually decreased in the first three months of this year, and in March there was an exchange for the position of the largest exporter, when Leram skipped Alliance Healthcare. While Leram is constantly growing, the volume of re-exports at Alliance Healthcare fell sharply, so that in January they amounted to almost 61 million crowns, in February 44 million and in March only less than 20 million crowns. As a result, Alliance Healthcare even moved up to third place, as DerStar Pharma CZ, sro (22 million in March) fought its way to second.

Alliance Healthcare is one of the top four distributors who supply medicines to Czech pharmacies nationwide. Three of them are associated in AVEL (Association of Drug Distributors), in addition to Alliance Healthcare it is also Phoenix and ViaPharma. Together, they occupy almost 80 percent of the market. The fourth is Pharmos.

Large distributors: Our primary interest is Czech patients

Alliance Healthcare re-exports completely openly. "It is a legal activity supported by the European Union," emphasizes Jan Rohrbacher, the company's executive and business director, saying that the European Commission is "angry" with the Czechia over the drug law, so distributors are preparing a complaint against the Czech Republic in this matter. "We do not comment on it, we have never been ashamed of our exports, we have partners in the Netherlands, England and elsewhere in Europe. The price difference is a problem for manufacturers, not ours. We export enough drugs. We would not dare provoke Czech patients or drug manufacturers to export drugs that are in short supply," adds Director Rohrbacher.

Question marks hung over the other three big players. At the same time, it was speculated that smaller companies that do not supply their own medicines to pharmacies export medicines abroad precisely for the benefit of wholesale distributors. The mechanism was to be such that the wholesaler would apply an increased trade surcharge, which is not commonly used among distributors, or more than three percent, and the drug would be exported by someone else. The deal pays off for everyone involved. The whole chain works with the knowledge of the manufacturer (marketing authorization holder). However, the wholesale distributors refuse to take part in such a thing, or say that the data published by SÚKL correspond to reality and that there are no hidden trades.

In the past, however, several independent sources told the Medical Journal that, for example, Phoenix, as the largest distributor of drugs in the Czech Republic, uses the Brno companies Leram and Pharmawell for re-exports. We asked everyone involved. Phoenix CEO Petr Doležal vehemently denied this information. "The information from SÚKL from DIS 13 is fine and there is nothing else or hidden. This means that we do not export. Pharmawell is nothing more than an ordinary small distributor who really takes goods from us in the order of one hundred thousand crowns. Leram does the same," said Doležal, emphasizing: "We are interested in supplying our customers and patients, our primary interest is not export. You will find those who do it relatively easily and unambiguously. "

Small distributors are silent

So if specialist re-exporters don't export bulk medicines they buy from wholesalers, where do they get them? They can agree directly with the manufacturers or marketing authorization holders. As our source from the pharmaceutical industry explained to us, the management of the Czech branch of the manufacturer can thus improve its results (higher sales) towards the headquarters, or thus improve itself financially, or thus obtain money for investments in marketing, where it uses the profit from re-export to training of doctors.

Leram, which is at the head of re-exporters in March (almost 39 million crowns a month), does not want to talk about its business at all. The company's executive Milan Kříž told the Medical Diary that they have decided not to respond to our questions. Among other things, we wanted to know the share of medicines that Leram obtains from wholesalers compared to those that it buys directly from pharmaceutical companies. We also asked Pharmawell the same questions. "We trade with all wholesale distributors, we do not buy directly from manufacturing companies," said Alice Dosedlová, chairwoman of the board of Pharmawell as.

Thus, it seems that the journeys of medicinal products, which were intended for Czech patients and eventually go abroad, are somewhat shrouded in a mysterious fog in the case of specialized export companies. However, the possibility that some re-export companies do not comply with the law cannot be ruled out. "Some well-known re-exporters are completely missing from the SÚKL survey. It is therefore a question of whether they stopped re-exports or whether they circumvent the methodologies and do not provide the data to the office, despite the threat of a fine," says Ondřej Moravec, sales director and board member of Pharmos, whom we also asked for an opinion.

The volume of re-exports is heading downwards. Is this a trend?

Indeed, the volumes exported by wholesalers in their own name (or in the name of their subsidiaries) are relatively small compared to companies specializing in exports. Leaving aside Alliance Healthcare, which is falling just as sharply, the other three wholesale distributors are orders of magnitude lower. ViaPharma, the successor to the Gehe brand, which is connected to the company Česká lékárna holding (pharmacy operator Dr. Max), exported drugs worth 8.4 million and Dr. Max Pharma sro for the same period for 9.5 million crowns. The largest distributor of Phoenix pharmacy wholesale, only 674 thousand crowns. Their subsidiary, the BENU Czech Republic pharmacy network, is "improving" their balance a bit, with almost two million.

The last of the big four, Pharmos, re-exported drugs worth two million crowns in three months. The comparison of figures from wholesale distributors with data on such exporters, such as 'Renata Batelková', a natural person doing business under the Trade Licensing Act based in the village of Troubsko, who exported products worth 8.3 million crowns from January to March (but rather it was cheap drugs).

As for the decline in re-exports in the first three months, the question is whether this is already a trend or still a random phenomenon. While in January the total volume of re-exported drugs amounted to 294 million crowns, in February it was seven million less (287 million crowns), in March even another 16 million crowns less (271 million crowns). "If we calculate the average return on re-export around 17 percent, we can easily calculate the profits of individual companies and the reasons why they are interested in re-export. Disclosure of data clearly causes them economic losses," comments Ondřej Moravec from Pharmos.

Jan Rohrbacher is not sure that this is a trend. "Hard to say. The options are different every month. Of course, we also reconsidered some things. Disclosure of a distributor's name may affect the overall volume of re-exports, but it's terribly difficult to estimate at this time. Direct exporters may either stop exporting because it bothers their suppliers, who would not supply them with medicines, or they will do so in some other way through some intermediaries, some other lesser-known distributors," says Alliance Healthcare, who also looks at the matter in the long run. "The volume of exports has not been growing for ten years, it is around four percent of the total pharmaceutical market. I don't think the problem with exports is related to the lack of drugs," he says.

The availability of medicines is deteriorating

Opinions differ on the effect of re-exports on the availability of medicinal products for Czech patients. It is definitely not widespread or fatal. However, it may relate to specific drugs and is more related to other factors. According to Pharmos's representative with DTP channels, according to the director of Alliance Healthcare, production and distribution problems at the global level are behind the possible unavailability of drugs.

"Pharmaceutical companies argue with the introduction of DTP, DTH channel (*DTP - direct to pharmacy, DTH - direct to hospital, ie direct deliveries of the manufacturer to pharmacies or hospitals - editor's note*) primarily to protect against re-exports and to provide drugs to Czech patients. However, the available data show that this system does not work. An example is the ophthalmic drug Lucentis from Novartis, which was exported in January in the amount of 1.4 million crowns. Other examples are Biogen (Benepali, Flixabi), Xeplion from Janssen, Remicade from MSD, Daxas from Astra Zeneca, or Grazax from ALK Slovakia. None of these products can be ordered in the standard distribution network and regular distributors do not have access to them," describes Ondřej Moravec from Pharmos.

The director of Alliance Healthcare thinks otherwise. "As for the hospitals where we supply mainly, I believe that DTH channels clearly restrict exports and determine that the drug will get where it is. These are mostly drugs limited by the manufacturer, specifically, of the eight thousand SÚKL codes, there are 900 drugs with a limit. We only get the limit, we can't order how much we want. We definitely do not export these drugs, precisely because there is a shortage of them," says Jan Rohrbacher.

However, according to Moravec, the connection of some pharmaceutical companies to one of the distributors is evident from SÚKL data. "A good example is NovoNordisk products, which are distributed in the Czech Republic by Alliance Healthcare and which is also their largest re-exporter. The situation is more paradoxical because other distributors as well as individual pharmacies have set limits on NovoNordisk's goods, which they can withdraw monthly. Paradoxically, the reason for these limits is to prevent re-exports," points out Pharmos's sales director.

However, Rohrbacher insists that re-exports do not endanger the availability of drugs for Czech patients. "Availability is monitored by SÚKL if there is a concern from both the manufacturer and

SÚKL that there is a shortage of a drug, there is a black list and exports are prohibited. All major distributors respect that. I don't know if everyone, even the small ones, but the big and well-known ones certainly do," says the director of Alliance Healthcare. He thus agrees with Ondřej Moravec from Pharmos on the use of the legal possibilities of the export ban. "It is therefore a question whether the DTP system really works as claimed by pharmaceutical companies and whether it is not better to use the means offered by law - to restrict / prohibit the re-export of products for which availability is limited under § 11 letter. q) of Act No. 378/2007 Coll., on Medicinal Products and on Amendments to Certain Related Acts (the Medicinal Products Act), as amended," Moravec believes.

Jan Rohrbacher does not overlook the poor availability of drugs, but sees the causes elsewhere than in re-exports or distribution channels. "The availability of medicines has deteriorated significantly recently. Especially from large generic companies. There are several reasons," says Rohrbacher. For example, production problems in Asia, where there are quality problems (for example, poor cartonning, ie the quality of paper, not medicine, but the whole batch is devalued) and where the overall international situation turns out, whether it was first covid or now the war in Ukraine. The mode of transport is changing, with aircraft replacing ships. And if pharmaceutical manufacturers can move production back to Europe, they can't find enough manpower for three-shift operations.

The most expensive drugs are exported by a farm company

The most expensive exports are made by one of the world's pharmaceutical companies, or its Czech branch Takeda Pharmaceuticals Czech Republic, for example in February over three thousand packages of medicinal products, with an average price of 57 thousand crowns. The most expensive of these was Revestive, which contains the active substance teduglutide, is made in Escherichia coli cells by recombinant DNA technology and is used to treat patients with short bowel syndrome. One package of this product costs 441,501 crowns (5 mg for injection in the price of the originator). Also, the other most expensive drugs are mostly from Takeda. The others are Cabometyx (treatment of kidney and liver cancer, Ipsen Pharma) for 77,590 crowns or Sprycel (treatment of leukemia, Bristol-Myers Squibb Pharma) for 59,690 crowns, which were exported by Leram and Saizen (growth hormone,

If we look at the total financial volume of medicines from Takeda, which she exported herself or distributors, then in three months it amounts to 156 million crowns. Behind it is Fresenius Kabi, which specializes in infusion, transfusion and clinical nutrition technologies. During the same period, their products were exported for 118 million crowns. "According to our findings, Takeda and Fresenius Kabi are not classic re-exports, but internal pre-sales between individual EU countries within the corporation," adds Ondřej Moravec, a picture of exports.

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