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HOT TOPIC

New requirements for entrepreneurs in connection with drug exports

The Law Amending the Law on Road Monitoring System of Goods' Shipments and Selected Other Laws became legal on 14 June. The monitoring of goods' shipments was extended to therapeutic products, medical products and special use food products which are listed on the specification of drugs at risk of shortage on the territory of the Republic of Poland. The Chief Pharmaceutical Inspectorate [PL: GIF] has published an announcement in which it explains entrepreneurs' new duties. According to these regulations, entrepreneurs (businesses) engaged in wholesale trade and those involved in the production and imports of medicinal products are now bound to notify GIF about the intention or execution of the following:

- export of goods outside the Polish territory
- sale of goods to an entity operating outside of the Polish territory

In particular, this requirement applies to entrepreneurs, who intend to repackage their products into foreign language packaging, either independently or by contracting the repackaging to a third party.

GIF may issue a decision prohibiting the export or sale of products exposed to shortages within 30 days of the notification on the export or sale of such products outside of the Polish territory. The absence of such objection by GIF within 30 days of the notice on the intention to export or sell the products means the therapeutic products, special purpose food products or medical products listed in the notice may be exported or sold abroad.

The entrepreneur is required to notify GIF about the actual export or sale transaction outside the Polish territory within 7 days of such development. See [here](#) for more.

The law imposes a new requirement on the entrepreneurs, obliging them to notify GIF about the means of transportation used for the activities subject to wholesale trade in therapeutic product permits and the permits to produce or import therapeutic products. See [here](#) for more.

Previous NFZ vice president for finances appointed as the new Deputy Health Minister. NFZ establishes a new position, that of deputy president for operations.

Łukasz Szumowski has appointed Maciej Miłkowski as deputy undersecretary of state at the Ministry of Health. Miłkowski is a graduate of the Warsaw School of Economics and has an MBA at the Kozminski University in Warsaw - Management and Economics of Medical Technology. He started his career in investment banking at Polski Bank Inwestycyjny. Since April 1998 he co-organized Mazowiecka Regionalna Kasa Chorych (a regional health insurance organization) and became its first member of the board for economic and administrative affairs and a CFO. He also managed the private clinic NZOZ Europejskiej Kliniki Rehabilitacyjnej VICTORIA for three years since 2002. Employed as director's representative for financial and accounting and deputy director for economic matters at the Mother and Child Institute hospital in 2005-2007. Deputy director for

economics at the Prymas Tysiąclecia Stefan Kardynał Wyszyński Institute of Cardiology between June 2007 and January 2016. Vice President of the NFZ for Financial Affairs since January 15, 2016.

Meanwhile, NFZ president Andrzej Jacyna has issued a decree dated June 15, 2018, amending the decree of June 15, 2018, on NFZ head office organizational bylaws. The decree establishes a new post of deputy NFZ president for operations, who will be supervising directly the Analysis and Strategy Department and the Department for Beneficiary Affairs. Up until now, the NFZ president had three deputies, for military/police affairs, financial and medical. See [here](#) for more. The NFZ has already announced a contest for the new position - see [here](#) for more

New colon cancer therapies are awaiting Health Minister's approval

Patients with advanced colon cancer have access to three treatment lines as part of the drug program. At present, the ministry is conducting proceedings to add three new drug therapies on the refundable drug lists, deputy health minister Marcin Czech said in response to a question by parliamentary deputy Marek Ruciński. Currently, as part of the 1st treatment line, patients have access to the following drug therapies:

- Cetuximab with chemotherapy following the FOLFIRI scheme
- Bevacizumab with chemotherapy following the FOLFIRI scheme
- Panitumumab with chemotherapy following the FOLFOX-4 scheme

Line 2 therapeutic schemes consist of the following:

- Bevacizumab with chemotherapy following the FOLFOX-4 scheme
- Aflibercept with chemotherapy following the FOLFIRI scheme

Therapies available under line 3 therapeutic scheme include: cetuximab monotherapy and panitumumam monotherapy.

The Health Ministry is currently proceeding refunds for the treatment of colon cancer that extend the indications for the use of bevacizumab as part of "Treatment of advanced colon cancer" drug program. The treatment will include the opportunity to add the first line of patients with V600E mutation in the BRAF gene to the treatment while retaining combined therapy that includes the use of bevacizumab and FOLFOXIRI scheme chemotherapy.

Work on details of the refund development mode continues

The Health Ministry and the Ministry of Entrepreneurship will offer preferences to corporations that decide to conduct research on new drugs in Poland. Work on regulations on the matter continues. Companies will receive easier access to refunds in return, Dziennik Gazeta Prawna daily wrote. The plan is to develop an algorithm to support companies, which have a special impact on the Polish economy. The assessment will include, among others, innovative activities and the impact on innovative ecosystem, the level of activity and the degree of manufacturing sophistication, the employment, exports and the taxes paid in Poland. "The main goal of refunds development mode is to support innovation at pharma companies and to facilitate wider access to new drugs and drug therapies to patients," the Minister of Entrepreneurship and Technology Jadwiga Emilewicz told the paper.

Statement on collaboration between the Health Ministry and patient organizations

The Health Ministry, Patients' Ombudsman and patient organizations have signed a statement on collaboration. "The dialogue with NGOs, both patient-focused and professional, is a priority for this health minister and for this government," deputy health minister Józefa Szczurek-Żelazko said. The deputy minister emphasized that the ministry wants the new solutions to be prepared "following a wide discussion" and accepted by the community. It is no less important, she said, that the proposals and comments made by the community be acceptable to the government. The purpose

of the statement is also to improve the quality of health care, protection of patients' rights and to popularize health education and prevention.

New president of the Polish Society of Vascular Surgery

Professor, Medical Sciences, Arkadiusz Jawień, Ph.D, became the President of the Polish Society of Vascular Surgery on June 15, for the 2018-2020 term. Jawień heads the Department of Vascular Surgery and Angiology and the Vascular Surgery Clinic and Angiology at the Medical Department, Collegium Medicum im. Ludwika Rydygiera in Bydgoszcz and is the co-founder and the Director of the Educational Center in the English Language at Collegium Medicum UMK. He specializes in general and vascular surgery and angiology.

Election of the Presidium of the Supreme Medical Council [PL: NRL] and the commission's chairman and the NRL team

On June 15 members of the Supreme Medical Council have elected NRL vice presidents, the treasurer, the secretary, deputy secretary, members of the NRL presidium and the chairmen of NRL commissions and teams. The eighth NRL presidium consists of the following:

- president NRL Andrzej Matyja
- vice president NRL Andrzej Ciśło
- vice president NRL Jacek Kozakiewicz
- vice president NRL Krzysztof Madej
- treasurer NRL Grzegorz Mazur
- secretary NRL Marek Jodłowski
- deputy secretary NRL Artur Drobniak
- presidium member NRL Michał Balsa
- presidium member NRL Jerzy Friediger
- presidium member NRL Dariusz Paluszek
- presidium member NRL Andrzej Wojnar

See [here](#) for more.

A Pole to head the Pharmaceutical Group of the European Union (PGEU)

Vice president of the Supreme Pharmaceutical Chamber, Michał Bylinak, was selected by PGEU as its president for 2019. PGEU is an organization of pharmacy community from 32 European countries. Its purpose is to represent the interest of its members, monitoring the law-making process and initiatives related to the pharma industry at an EU level. Its representatives are permanently in touch with the European Commission and the European Parliament authorities.

THE ECONOMY

According to GUS estimates, in May 2018 the prices of consumer goods and services rose by 0.2% compared to April 2018. Prices were up by 1.7% compared to May 2018. As expected, on a monthly basis, the prices of clothing and footwear and recreation fell by 0.4% and 1.0% respectively due to seasonal factors. Food prices also registered a decline, by 0.3%. May was another month in which the price of transportation services rose much faster than expected, by 2.6%.

The average salary growth in May within the corporate sector remained at 7% level on a year-on-year basis while the level of employment rose by more than 3%, the Main Office of Statistics said.

These results are lower than in April, when the average wages were up by 7.8% on a national level. Average employment among companies with 10+ employees has reached PLN 4696.59 before tax and was 3% lower than the month before. Due to the surprisingly low CPI inflation in May (just 1.7% y-o-y), real salary growth at large companies remained at a relatively high level of 5.17% (y-o-y).

Poland is the 30th among the 35 OECD countries in PwC's Golden Age Index, which assesses the level of use of potential of people aged 55 and more on the labor market. Poland's place near the bottom of OECD ranking is the product of several factors. The employment rate of people aged 55-64 in Poland is one of the lowest in the countries surveyed, at 46.2% in 2016 (an increase from 44.4% in 2015), with merely 9.9% workforce participation rate in the 65-69 age group. The average effective age of exiting the labor market, at 61.2 years, has changed only marginally compared to 61 in 2015. According to PwC experts, if OECD countries managed to boost their employment rates to match the rates registered in New Zealand (76.1% in 2016), the GDP of these countries in the long term would rise by as much as USD 3.5tn. For Poland, this would represent an increase of the GDP by USD 66bn.

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