DLA Piper Poland

Life Sciences

Monthly Brief |December 2022

DLA PIPER

The Strategy of the State Pharmaceutical Inspectorate for 2023 - 2026

On 21 December 2022, the Strategy of the State Pharmaceutical Inspectorate for 2023 - 2026 was published on the website of the Chief Pharmaceutical Inspectorate (GIF). The document aims to improve the efficiency of the State Pharmaceutical Inspectorate and preparing it for the challenges of the coming years.

Based on a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis, the document lists six main areas for action: (i) the standardisation of processes, (ii) the automation of the GIF, (iii) the improvement of supervision of the availability of medicinal products, (iv) the development of external communication, (v) the optimisation of operating costs, and (vi) activities aimed at improving the conditions of employment in the State Pharmaceutical Inspectorate.

The analysis carried out in order to prepare the strategy was conducted with consideration of various perspectives, including those of stakeholders and specific external actors. According to the GIF, the strategy is intended to be a document subject to cyclical reviews and updates, so that it meets the real needs of the contemporary pharmaceutical market.

The strategy can be accessed via the link below.

Link

Clinical trials

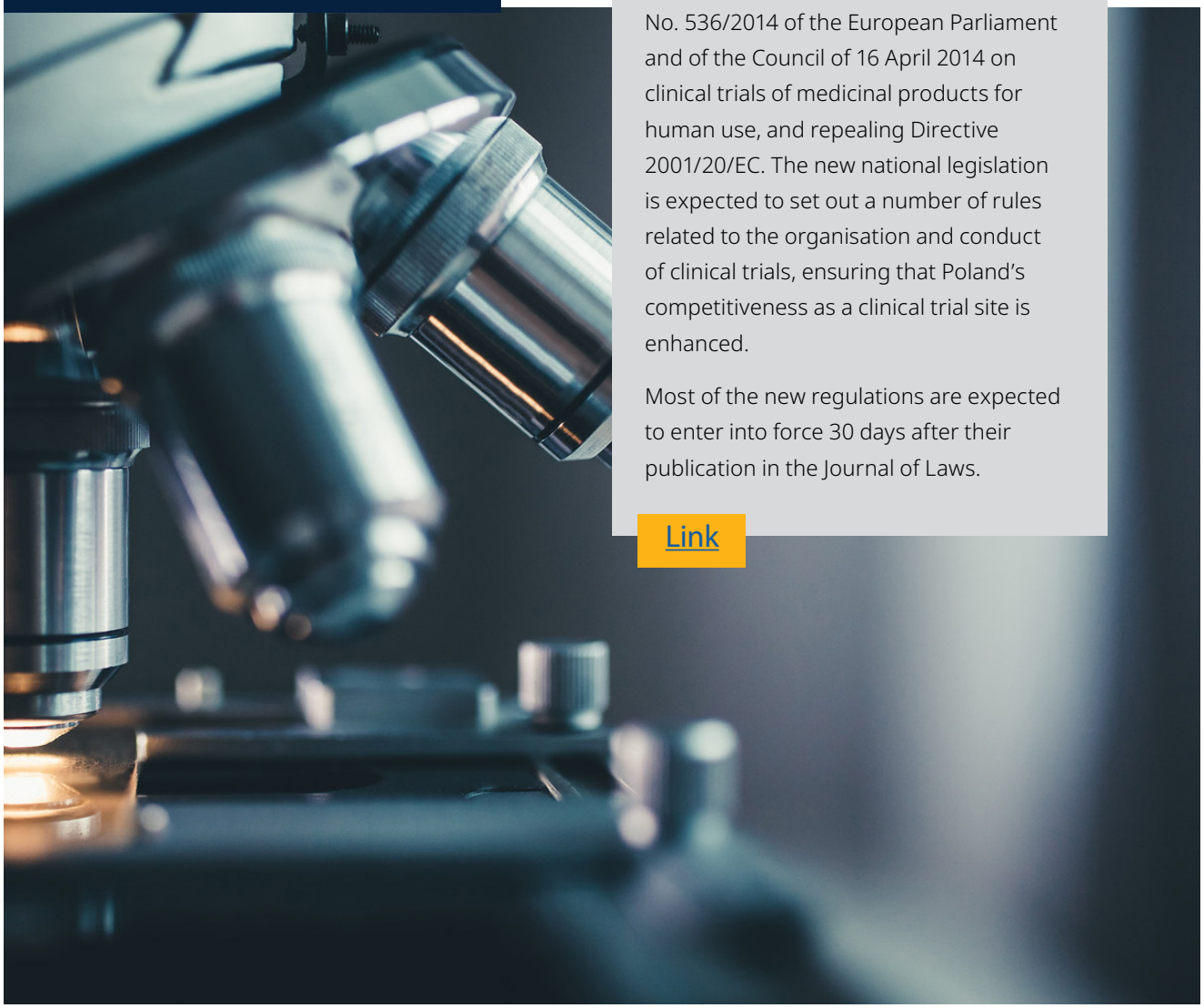
Bill on clinical trials referred to the Health Committee

In November's brief, we mentioned that the government had adopted a bill on the clinical trials of medicinal products for human use. The bill then went to the Sejm (the lower house of the Polish Parliament), where it was supported by a majority of MPs at a meeting on 14 December (437 votes against rejecting the bill on the first reading compared to 15 votes in favour). The bill was then referred to the Health Committee (*Komisja Zdrowia*), which prepared a report on its analysis.

The bill was developed to ensure the application in Poland of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use, and repealing Directive 2001/20/EC. The new national legislation is expected to set out a number of rules related to the organisation and conduct of clinical trials, ensuring that Poland's competitiveness as a clinical trial site is enhanced.

Most of the new regulations are expected to enter into force 30 days after their publication in the Journal of Laws.

Link



Regulation on the compulsory insurance of the sponsor and investigator of a clinical trial of a medical device

On 16 December 2022, the President of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) issued an announcement on the entry into force of the regulation of the Minister of Finance on the compulsory insurance of the sponsor and investigator of a clinical trial of a device or an in vitro diagnostic medical device performance study.

The regulation was published in the Journal of Laws on 9 December. It specifies the detailed scope of the insurance, the date when the insurance obligation arises, and the minimum insurance coverage amount.

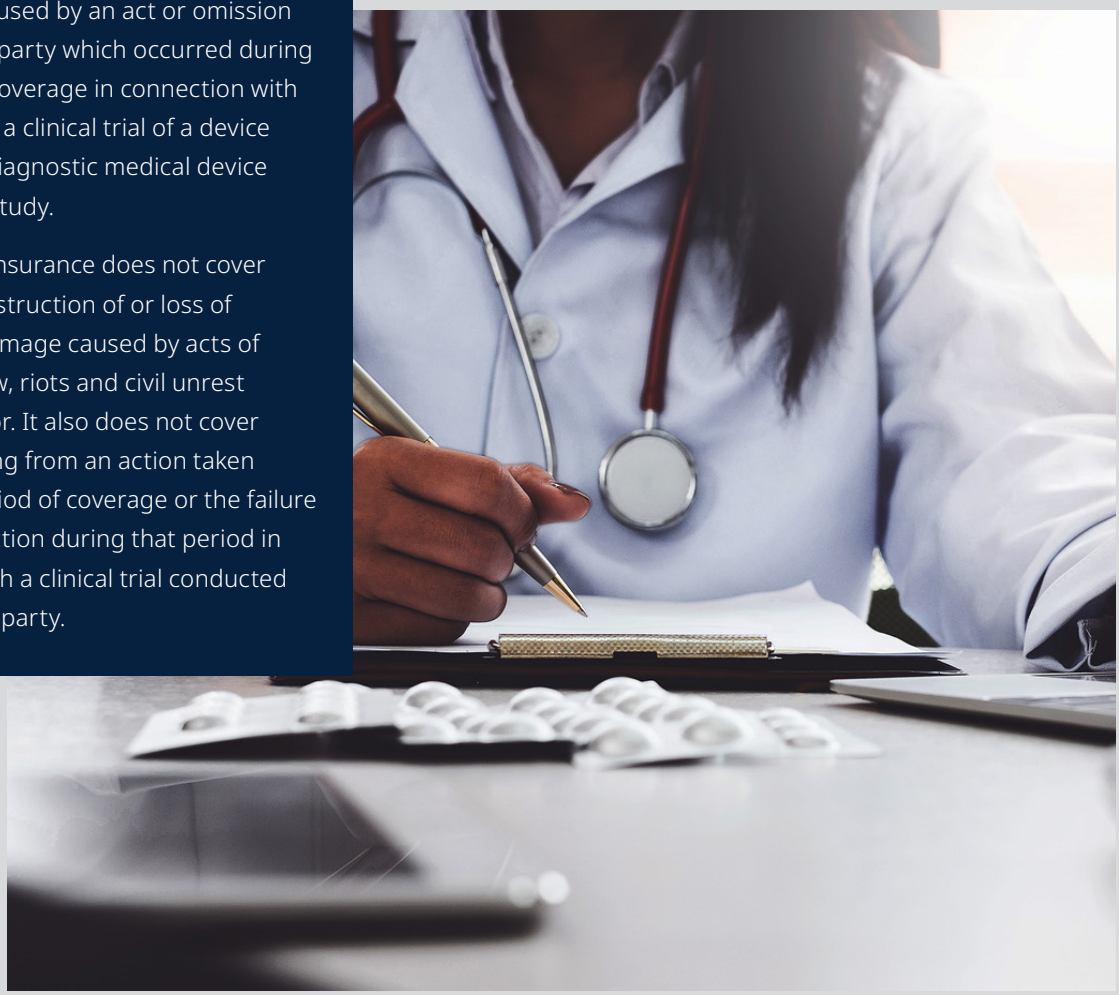
Under the regulation, the insurance covers the liability of the sponsor and investigator for damage caused by an act or omission of the insured party which occurred during the period of coverage in connection with the conduct of a clinical trial of a device or an in vitro diagnostic medical device performance study.

However, the insurance does not cover damage to, destruction of or loss of property or damage caused by acts of war, martial law, riots and civil unrest or acts of terror. It also does not cover penalties arising from an action taken during the period of coverage or the failure to take such action during that period in connection with a clinical trial conducted by the insured party.

The minimum coverage amounts per event covered by the insurance contract are dependent on the number of subjects in the trial and are set out in the regulation jointly for the sponsor and the investigators participating in the trial.

The regulation entered into force on 10 December 2022.

Link



Hemp and hemp-derived products

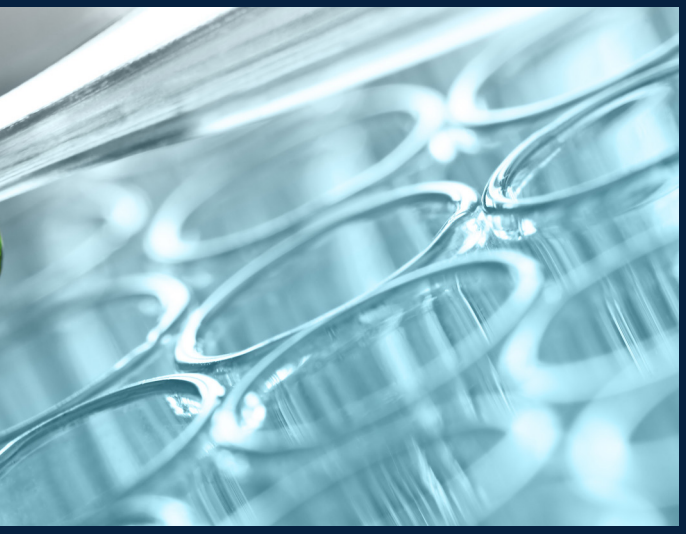
Chief Pharmaceutical Inspector on the legal status of hexahydrocannabinol (HHC)

Driven by the rapidly increasing number of enquiries about hexahydrocannabinol (HHC), the Chief Pharmaceutical Inspector issued a communication on the legal status of the substance on 20 December.

The communication explains that HHC is indicated in Annex 1 to the Regulation of the Minister of Health of 17 August 2018 on the list of psychotropic substances, narcotic drugs and new psychoactive substances as a Group I-P psychotropic substance (item 96) and appears in that annex under the name (6aR, 10aR)-6a,7,8,9,10,10a-hexahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol.

In practice, this means that HHC is a controlled substance and its possession, use, manufacture, alteration, processing, distribution and any other activities related to it are covered by anti-drug legislation.

Link



Cosmetics

Results of official inspections of cosmetics wholesalers and shops in Poland

On 9 December, the website of the Office of Competition and Consumer Protection (UOKiK) published information on the results of inspections conducted at places of sale of cosmetics. Inspectors checked 255 wholesalers and shops and found irregularities in almost half of them.

The inspection covered both small drugstores and chain stores. Almost 2,000 batches of products were checked and objections were raised with respect to 38% of them, the most common being the lack of or incorrect information on ingredients and the function of the product, as well as products being past their expiry date.

In addition, the inspectors checked whether cosmetics contained other information required by law, such as shelf life, weight, volume and special precautions, as well as the indication of the batch number and the person responsible for the product. The descriptions of ingredients were analysed for inadmissible substances and the marketing claims were checked for veracity.

As a result of the inspections, fines of almost PLN 70,000 were imposed on the infringers, 112 notifications were submitted to the Sanitary Inspectorate, and five products were withheld or withdrawn. A list of the products in question together with a well-presented and easily readable inspection report can be found on the UOKiK website at the following address.

Link

Healthcare

New Act on the Profession of Paramedic

On 21 December, the Act of 1 December 2022 on the Profession of Paramedic and the Professional Body for Paramedics was published in the Journal of Laws.

Until now, regulations concerning the paramedic profession were contained in the Act on State Medical Rescue Services. As indicated in the justification of the original bill, the intention is to introduce into the legal system provisions comprehensively regulating the paramedic profession and to create a legal framework for the operation of the professional body for paramedics.

The Act is to achieve this goal by defining, among other things, the principles and conditions for practising the profession of paramedic, the issue of postgraduate training and in-service training of paramedics, the organisation and scope of the professional body for paramedics, as well as the principles of professional liability of paramedics.

Most of the provisions of the Act will enter into force six months after the date of publication, with the exception of certain amending and transitional provisions.

Link

Amendment to the Medical Fund Act

The Act of 1 December 2022 amending the Medical Fund Act and certain other acts was published in the Journal of Laws on 19 December. The legislative work on the amendment was initiated by a bill presented by the President.

The new provisions concern, among other things, support for actions related to the prevention of infectious diseases, in particular through the purchase of vaccines for recommended preventive vaccinations within the framework of the Preventive Vaccination Programme referred to in the Act on Preventing and Combating Infections and Infectious Diseases in Humans, as well as enabling support for preventive actions and accompanying educational and promotional activities.

Among the solutions introduced by the amendment is an increase in the Medical Fund's spending limit, the addition of new categories of services, including gene diagnostics for children and adolescents and investment in innovative medical devices. The final wording of the Act is partly the result of amendments by the *Senat* (the upper house of the Polish Parliament) which were subsequently accepted by the Sejm (the lower house of the Polish Parliament).

Link

Amendment of the Act on the Professions of Physician and Dentist

In the second half of December, work on the introduction of the Act amending the Act on the Professions of Physician and Dentist and certain other acts came to an end. The Act, passed after intensive discussions in the Polish Parliament, was published in the Journal of Laws on 27 December.

As we discussed in detail in our November brief, the new regulations concern the optimisation of public spending on healthcare within the total amount of outlays in this area, determined annually on the basis of the provisions of the Act on Healthcare Services Financed from Public Funds, as well as incidental regulations, which are related to the need to support the healthcare system after a period of intensified activities aimed at counteracting and preventing COVID-19.

The Act will enter into force on 1 January 2023, with the exception of the explicitly indicated provisions, which entered into force on the day following the date of publication, i.e. on 28 December 2022.

Link

Bill on quality in healthcare adopted by the government

1

The bill on quality in healthcare and patient safety, which has been under preparation in the Government Legislation Centre since July 2021, was adopted by the Council of Ministers on 13 December 2022 and referred to the *Sejm* (the lower house of the Polish Parliament), where it is currently awaiting its first reading.

2

The bill sets out the principles of the healthcare quality and patient safety system, providing for comprehensive solutions in the areas of: authorisation, internal quality and safety assurance systems, accreditation, compensation benefits system, and medical registers. Currently, quality issues in healthcare are regulated in a number of legal acts.

3

The bill addresses the tasks, responsibilities and powers of the various actors in monitoring, assessing and improving quality. As the authors of the bill point out, the new regulations will give patients, medical professionals and healthcare providers access to universal, reliable, objective and comparable information on the quality of healthcare provided.

The bill can be viewed on the *Sejm's* website at the following link.

Link

Changes to the draft of the so-called ’big amendment’ to the Reimbursement Act

On 19 December, a new version of the draft of the so-called ‚big amendment’ to the Reimbursement Act, i.e. the Act amending the Act on Reimbursement of Medicines, Foodstuffs for Special Dietary Purposes and Medical Devices and certain other acts, was published on the website of the Government Legislation Centre.

Among other things, the authors of the updated document have removed the provision on the introduction of price corridors - a legal construction according to which the official price of a reimbursed equivalent of a medicine could not exceed 150% of the price of the cheapest equivalent.

In addition, the following proposals were dropped: the obligation to supply products reimbursed in the pharmacy channel in equal quantities to at least 10 entities operating pharmaceutical warehouses; the possibility to request payment of the price difference in the event of changes in the prices of reimbursed products; the specification of the limit group in the reimbursement decision; the possibility for a social organisation to join the reimbursement proceedings with the consent of the applicant; and the obligatory repeal of a reimbursement decision in the event of failure to meet the obligation concerning continuity of supply within 14 days of the entry into force of the reimbursement decision and in the event of failure to submit reimbursement applications for all other forms of a reimbursed medicine that are placed on the market.

Some voices from the pharmaceutical sector stress that the above amendments are not the only ones that should be included in the amendment. In particular, there are demands to increase National Health Fund (NFZ) drug subsidies and to introduce an effective mechanism to increase drug production in Poland.

Link

Bill amending the Mental Health Act: changes also planned for psychotherapists

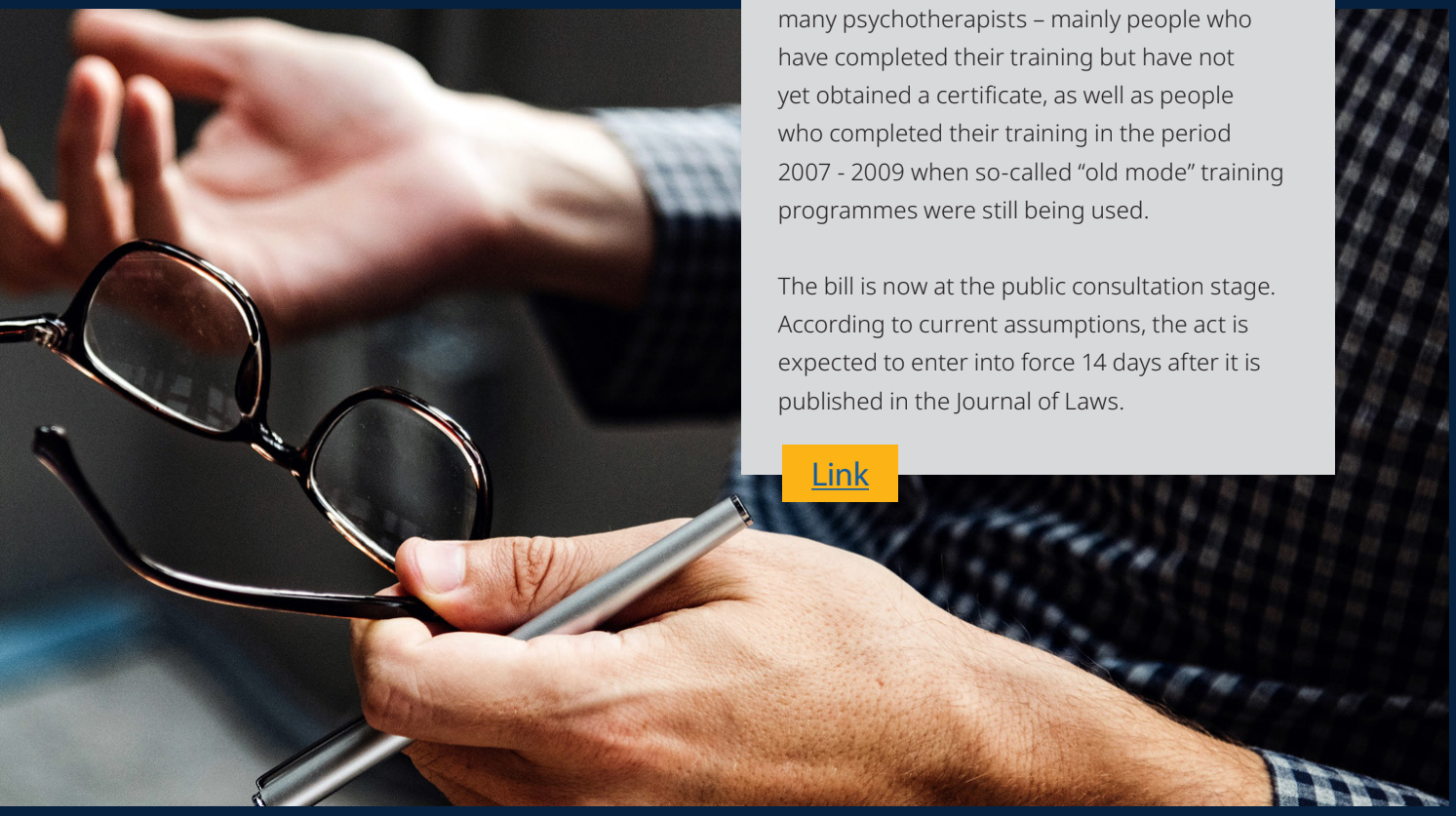
On 16 December, the bill amending the Mental Health Act of 1994, was published on the website of the Government Legislation Centre.

The proposed amendments include a modification of the terminology used throughout the Act, which is archaic and may contribute to the stigmatisation of people affected by mental disorders, as well as changes in the provisions concerning the use of physical coercion against such people. The amendments also aim to remove possible doubts of interpretation, i.e. to clarify issues concerning the parties to court proceedings in cases of the admission of a person with mental disorders to a psychiatric hospital without their consent and their discharge therefrom, and also issues concerning the venue of the court hearing.

Importantly, the bill also proposes definitions of the terms psychotherapist and psychotherapy. Consequently, only a psychotherapist, understood as a person who fulfils all the conditions specified for *a person holding a psychotherapist certificate, referred to in the regulations on guaranteed services in the field of psychiatric care and addiction treatment issued on the basis of Article 31d of the Act on Healthcare Services Financed from Public Funds, or a person who is a specialist in psychotherapy of children and adolescents, will be able to conduct psychotherapy within the* framework of primary and specialised healthcare. Shortly after the publication of the bill, the Polish Council for Psychotherapy pointed out that the definition formulated in this way excludes many psychotherapists – mainly people who have completed their training but have not yet obtained a certificate, as well as people who completed their training in the period 2007 - 2009 when so-called “old mode” training programmes were still being used.

The bill is now at the public consultation stage. According to current assumptions, the act is expected to enter into force 14 days after it is published in the Journal of Laws.

Link



Medicinal products

Difficult start for the official list of medicine shortages

At the end of November, doctors and pharmacists in Poland received a list of medicines with reduced availability prepared by the Chief Pharmaceutical Inspectorate (GIF). According to the announcement made by representatives of the Ministry of Health, such lists will be drawn up and sent out regularly, at two-week intervals. Their aim is to counteract the problem of limited availability of medicines.

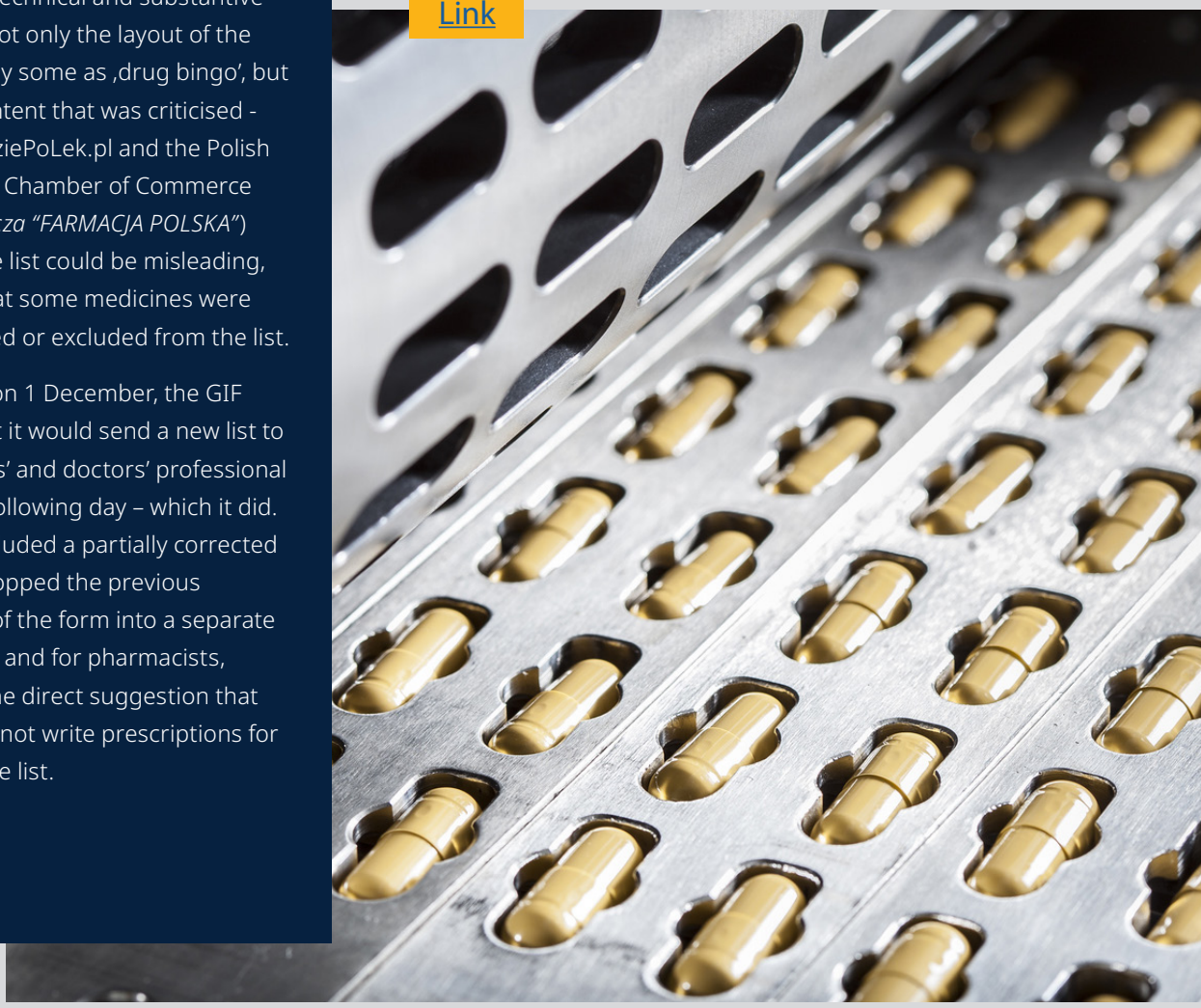
However, the first edition of the list met with criticism. Shortly after its release, public comments were made concerning its inadequate technical and substantive quality. It was not only the layout of the list, described by some as ‚drug bingo', but above all its content that was criticised - the website GdziePoLek.pl and the Polish Pharmaceutical Chamber of Commerce (*Izba Gospodarcza "FARMACJA POLSKA"*) warned that the list could be misleading, pointing out that some medicines were wrongly included or excluded from the list.

Consequently, on 1 December, the GIF announced that it would send a new list to the pharmacists' and doctors' professional bodies on the following day – which it did. The new list included a partially corrected set of items, dropped the previous differentiation of the form into a separate one for doctors and for pharmacists, and removed the direct suggestion that doctors should not write prescriptions for the drugs on the list.

After two weeks, on 16 December, the GIF prepared another list of medicines with limited availability addressed to the pharmacists' and doctors' professional bodies, this time including more products with antibiotics. At the same time, a commentary on the methodology for preparing the list and the phenomenon of temporary shortages of medicinal products in Poland itself was posted on the GIF's website.

In the words of Edyta Janczewska-Zreda, GIF spokeswoman, *"We want to develop material that will actually serve pharmacists and doctors. We approach this with the utmost responsibility and we also expect such responsibility from all those who have an impact on the situation of drug availability for patients.".*

Link



Veterinary

New Act on the Animal Identification and Registration System

The new Act on the Animal Identification and Registration System adapts Polish law to the requirements under Regulation 2016/429 (the so-called „Animal Health Law"). We wrote about the details of this legislation in our November Life Sciences Monthly Brief (available at this link)., The Act was published in the Journal of Laws on 22 December 2022 and came into force on 6 January 2023.

Link

New Act on Feed Law and Waste Law

The act provides for the adaptation of Polish law to the regulations of the European Union, in particular to the obligations under Regulation 2019/4 (the so-called „Feed Regulation"). The purpose of the amendment is to standardise the requirements to be met by entities operating in the feed market and in accordance with which they may manufacture, store and transport medicated feed or intermediate products.

The act stipulates that provincial veterinarians will generally be the competent authorities for obligations under the Feed Regulation, as well as for official inspections of medicated feed. They will also issue administrative decisions on the approval of establishments, as well as their deletion.

The act also establishes rules for handling unused or expired medicated feeds, which constitute veterinary waste.

The act also provides for the introduction of sanctions for a number of improperly undertaken activities, including, for example, the manufacture of medicated feeds contrary to the requirements set forth in the Feed Regulation, the failure to maintain proper documentation, or the failure to label medicated feeds placed on the market.

The ban on the manufacture, marketing and use in animal nutrition of genetically modified feeds and genetically modified organisms intended for feed use is set to come into force on 1 January 2025.

The act is expected to enter into force 14 days after its promulgation except for the ban on GMO feeds mentioned above.

Link

118th meeting of the European Medicines Agency Management Board

The meeting was held on 14 - 15 December in Amsterdam. In addition to panels on recent activities related to the response to the COVID-19 pandemic, the adoption of the budget, and knowledge sharing regarding the Clinical Trials Information System (CTIS), which will be launched on 31 January 2023, the Management Board also adopted the latest progress reports on the adaptation of Regulation 2019/6 (the so-called „Veterinary Medicines Regulation").

Over the past few years, the Union Product Database (UPD), the modernised pharmacovigilance reporting system and safety signal management have been delivered. In the near future, it is planned to complete the data upload into the UPD and further to enriching these data. The Management Board also addressed the implementation of the EU Veterinary Big Data strategy.

For more information, please visit the European Medicines Agency website:

Link

Food

Draft regulation on enrichment substances added to food

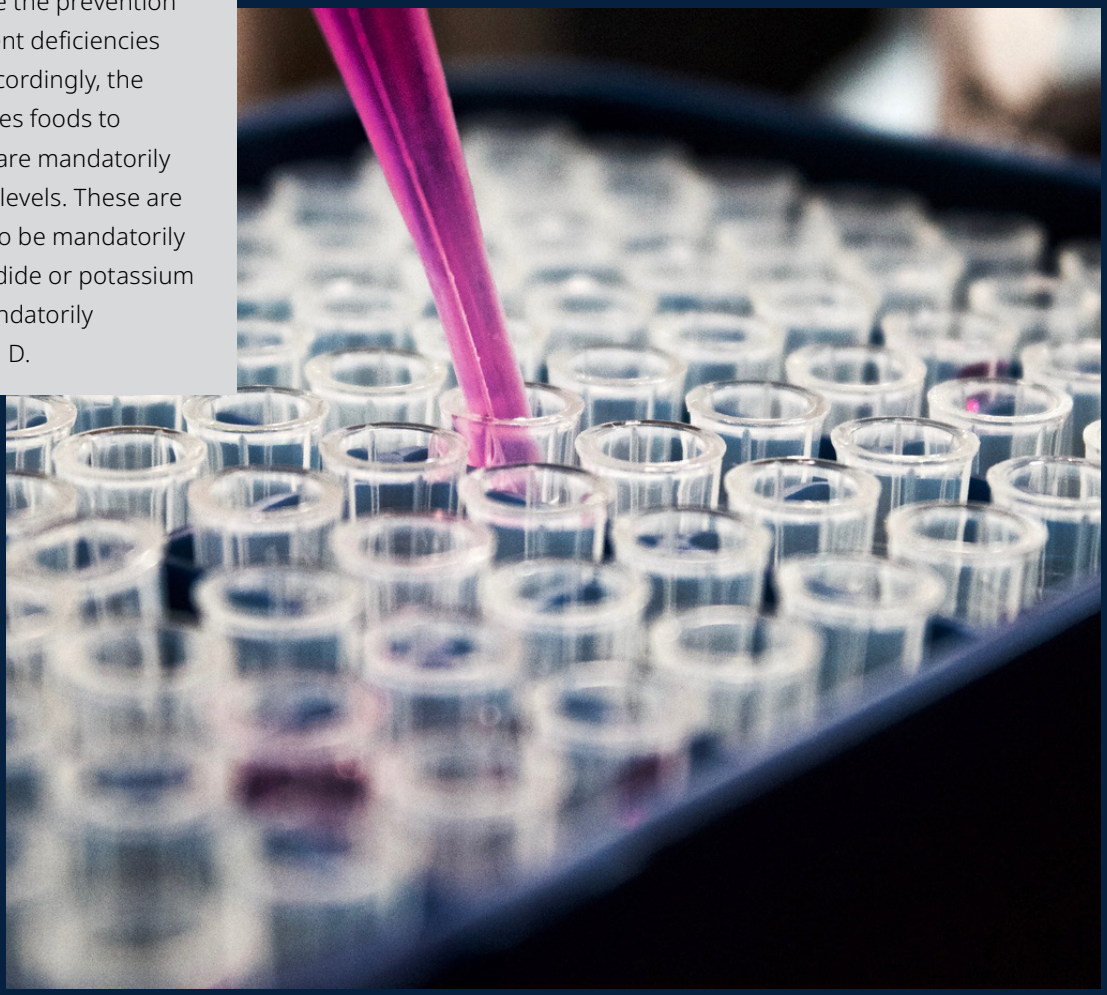
On 7 December, a draft regulation of the Minister of Health on enrichment substances added to food was published on the website of the Government Legislation Centre. The draft is being developed on the basis of the Polish Food and Nutrition Safety Act, and in line with EU Regulation (EC) No. 1925/2006, which, in regulating food enrichment in the European Union, allows Member States to maintain national legislation on the mandatory enrichment of certain food groups.

As indicated in the justification of the draft, the aim of the regulation is to maintain existing measures to ensure the prevention and compensation of nutrient deficiencies in the Polish population. Accordingly, the proposed regulation specifies foods to which vitamins or minerals are mandatorily added, and their maximum levels. These are envisaged to be table salt, to be mandatorily enriched with potassium iodide or potassium iodate, and certain fats, mandatorily enriched with vitamin A and D.

In addition, the draft includes a list of substances other than vitamins and minerals prohibited in the production of food.

The draft is currently subject to public consultation. Its full content is available on the website of the Government Legislation Centre at the following link.

Link



Draft regulation on model documents for the registration and approval of establishments manufacturing or placing food on the market

A draft regulation of the Minister of Health on model documents for the registration and approval of establishments producing or placing on the market food and materials and articles intended to come into contact with food, subject to official control by the State Sanitary Inspection authorities, was submitted for public consultation.

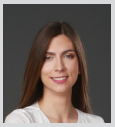
The regulation presents a template of the register of establishments subject to official inspection by the State Sanitary Inspection authorities („the register of establishments"), a template of the certificate of entry in the register of establishments, and templates for applications for:

- the approval of an establishment and entry in the register of establishments,
- making changes to the register of establishments,
- removing an establishment from the register of establishments.

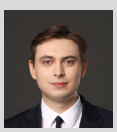
It is envisaged that the regulation will enter into force 14 days after its publication in the Journal of Laws. The current wording of the draft can be viewed on the website of the Government Legislation Centre at the following link.

Link

Andrzej Balicki, Ph.D.
Partner
Head of Life Sciences, Poland
andrzej.balicki@dlapiper.com



Jolanta Dąbrowicz
Senior Associate
Life Sciences
jolanta.dabrowicz@dlapiper.com



Przemysław Matuszewski
Junior Associate
Life Sciences
przemyslaw.matuszewski@dlapiper.com

Urszula Grębowska
Paralegal
Life Sciences
urszula.grebowska@dlapiper.com

www.dlapiper.com