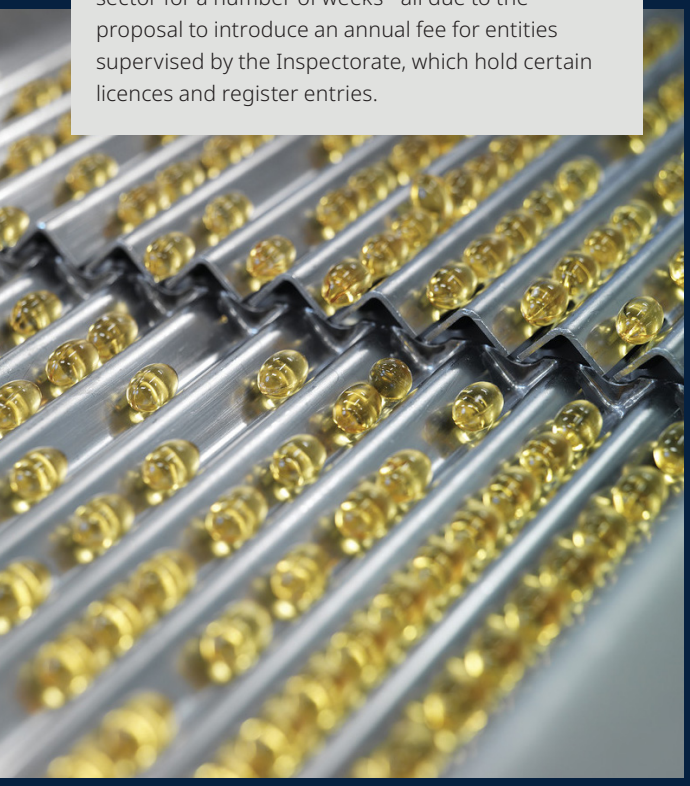
Poland | Life Sciences Monthly Brief | November 2022

Annual fees for participants in the pharmaceutical market? Bill amending the Pharmaceutical Law and certain other acts

We first wrote about the planned amendments to the Pharmaceutical Law and certain other acts (the so-called *Verticalisation Act*) in September 2022, when the principles for the amendments were announced in the list of legislative work of the Council of Ministers. On 3 November, the text of the bill was made available on the website of the Government Legislation Centre (*Rządowe Centrum Legislacji*, RCL). The bill is currently at the public consultation stage.

The planned changes concern the organisation of the State Pharmaceutical Inspectorate, the competences of the bodies performing its tasks, and the financing of the supervision of the pharmaceutical market. This financing has been the subject of lively discussion in the pharmaceutical sector for a number of weeks - all due to the proposal to introduce an annual fee for entities supervised by the Inspectorate, which hold certain licences and register entries.



The Ministry of Health has proposed the following annual fees:

- **PLN 250** per licence to run a "**pharmacy point**" (*in Polish: punkt apteczny*);
- **PLN 500** per licence to operate a **pharmacy open to the public**;
- **PLN 1,000** per licence to operate **a pharmaceutical warehouse** or to be entered in the **National Register of Drug Intermediaries**;
- **PLN 3,000** per licence to **manufacture or import medicinal products** or to be entered in the **National Register of Manufacturers, Importers and Distributors of Active Substances**.

According to the bill, these fees would be additionally increased by **0.02% of the revenue** obtained by the given entity in the **previous tax year.**

In response to this proposal, on 7 November, the Presidium of the Supreme Pharmaceutical Council (*Naczelna Rada Aptekarska,* NRA) held an extraordinary meeting, during which it prepared an opinion expressing objections to the new fees and appealing to the Minister of Health and the Minister of Justice to remove from the bill the provisions obliging pharmaceutical warehouses, pharmacies and "pharmacy points" to pay them.

On 15 November, another critical opinion on the planned introduction of annual fees was published – this time by representatives of ten pharmaceutical market organisations. The opinion took the form of a joint appeal to the Prime Minister, the Minister of Health and the Chief Pharmaceutical Inspector submitted by: PZPPF National Producers of Medicines, the "Farmacja Polska" Economic Chamber, the Polish Association of Self Medication Industry (PASMI), the Polish Chamber of the Pharmaceutical Industry and Medical Devices (POLFARMED), the Association of Employers of Pharmaceutical Wholesalers, the Employers' Union of Innovative Pharmaceutical Companies INFARMA, the Lewiatan Confederatiom, the Union of Entrepreneurs and Employers (ZPP), the Supreme Pharmaceutical Council and the Healthcare Committee of the Federation of Polish Enterprises.

The next stage of legislative work on the bill will be the publication of the opinions reported during the public consultations and the preparation of a report containing the legislator's assessment of them. The adoption of the bill by the Council of Ministers is scheduled for the fourth quarter of 2022.

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Link to the bill on the government website

Opinion of the Presidium of the NRA

Opinion of pharmaceutical market organisations

Pharmacies and pharmacists

New requirements for pharmacists coming soon - the publication of the Regulation on the basic conditions for running a pharmacy

On 18 November 2022, the Regulation of the Minister of Health of 27 October 2022 on the basic conditions for running a pharmacy was published in the Journal of Laws. While still at the draft stage, the document had already sparked controversy among pharmacists, as evidenced by the appeal not to sign the regulation, which was addressed to the Minister of Health by the President of the Supreme Pharmaceutical Council (*Naczelna Rada Aptekarska*) at the beginning of November 2022.

Among the new obligations introduced by the Regulation, the most important concern the provision of 24-hour temperature and humidity monitoring and equipment eliminating excessive sunlight in certain pharmacy premises, as well as storing certain categories of medicines in such a way as to ensure their separation from other products. Furthermore, under the Regulation, pharmacies will have to comply with new requirements regarding record-keeping systems and procedures.

The Regulation will come into force on 3 December 2022, 14 days after its publication in the Journal of Laws. Pharmacy operators should be mindful of the time that they have to meet the new obligations - these are 12 months for obligations regarding the use of devices and measuring equipment and six months for the remaining obligations.

Link to the Regulation in the Journal of Laws

Planned amendment to the code of ethics for pharmacists

The Supreme Pharmaceutical Council (*Naczelna Rada Aptekarska*, NRA) is working on amendments to the Code of Ethics of Pharmacists of the Republic of Poland, applicable - according to its current wording - to all pharmacists active in Poland. The deadline for submitting proposals for issues that should be regulated or clarified expired at the end of November 2022.

As highlighted by the NRA, the comments made will be forwarded to and discussed by the ‚Team for the development of proposals for amendments to the Code of Ethics of Pharmacists of the Republic of Poland', which was set up specifically for this purpose in May this year.

The current version of the Code of Ethics was created in 2012 and the need to adapt its content to changing legislative, technical and social circumstances has been discussed in the Polish pharmaceutical sector for several years. In particular, the expected changes concern the regulation of various online activities of pharmacists, including their presence on social media. There have also been calls to change the name of the code itself.

Link to NRA's announcement

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Medicinal products

Bill on clinical trials adopted by the government

At its meeting on 22 November, the Council of Ministers adopted a bill on clinical trials of medicinal products for human use. The bill, which has been under preparation in the Government Legislation Centre since April 2021, has been drafted to ensure the national implementation of Regulation (EU) No. 536/2014 on clinical trials of medicinal products for human use, which also repeals EU Directive 2001/20/EC.

The bill sets out a number of rules related to the conduct of clinical trials in Poland, including:

1. the procedure for issuing an authorisation for a clinical trial on a medicinal product for human use and an authorisation for a substantial modification of a clinical trial;
2. the tasks of the Supreme Bioethics Committee for Clinical Trials and the procedure for its appointment;
3. the rules and procedure for being entered on and removed from the list of bioethics committees authorised to conduct ethical evaluations of clinical trials;
4. the rules and procedure for conducting an ethical evaluation of a clinical trial;
5. the responsibilities of the sponsor, principal investigator and investigator;
6. the rules of civil liability of the investigator and the sponsor;
7. the rules of the functioning of the Clinical Trial Participants Protection Fund;
8. the amount and manner of payment of fees related to a clinical trial;
9. the rules of financing healthcare services related to a clinical trial;
10. the rules and procedure for conducting clinical trial inspections

According to the authors of the bill, the aim of the new legislation is to increase Poland's competitiveness as a clinical trial site by implementing a transparent system of legal regulations, free of administrative barriers.

The next stage of legislative work is the submission of the bill to the Sejm (the lower house of the Polish Parliament). Most of the new provisions are to come into force 30 days after being published in the Journal of Laws.

Link to the bill on the government website

Changes to the Supplement to the 12th edition of the Polish Pharmacopoeia from 1 June 2023

On 23 November 2022, the Official Journal of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (*Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*, URPL) published an announcement from the President of the URPL on the date from which the requirements set out in Supplement to the 12th edition of the Polish Pharmacopoeia („FP XII") will apply.

This date is 1 June 2023, which will mark the commencement of the so-called "national requirements", i.e. those without equivalents in the European Pharmacopoeia, contained in the following sections of Supplement to the 12th edition of the Polish Pharmacopoeia: "National monographs", "Dosage list" and „List of very potent substances, potent substances and narcotics".

Together with the European Pharmacopoeia, the Polish Pharmacopoeia defines, in accordance with paragraph 1 of Article 25 of the Pharmaceutical Law, the basic quality requirements and test methods for medicinal products and their packaging and for pharmaceutical raw materials. As the President of the URPL points out, this document, which provides recognised, common standards for the quality of medicinal products and their components, is an important element of the system for ensuring the safe use of medicinal products by patients. The unified pharmacopoeial requirements facilitate the proper functioning of the global pharmaceutical market.

Link to the announcement

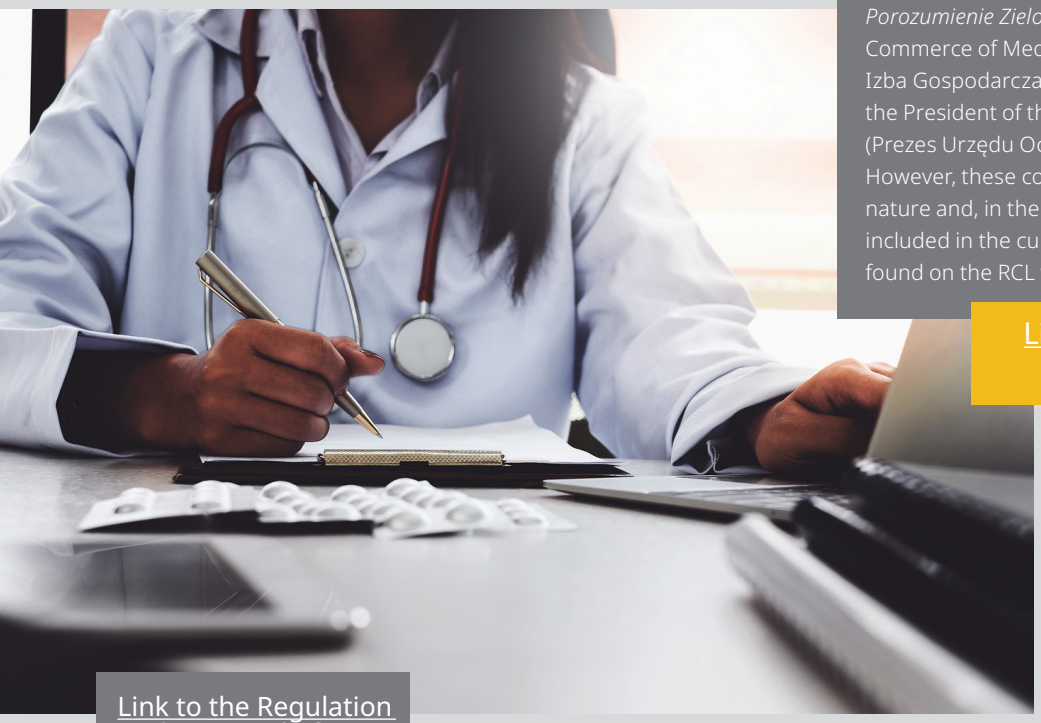
Medical devices

Amendment to the Regulation on the list of medical devices issued on prescription published in the Journal of Laws

On 15 November 2022, the Regulation of the Minister of Health of 27 October 2022 amending the Regulation on the list of medical devices issued on prescription was published in the Journal of Laws. The final wording of the amendment is the result of a legislative process that involved representatives of numerous patient groups and medical professions. With their interests in mind, the Minister of Health has taken into account some of the more than two hundred opinions expressed during the public consultation process.

The main changes introduced by the Regulation are the new limits on co-payments, which will benefit, among others, stoma patients, diabetes patients and people with disabilities. The amendment also specifies in more detail who will be authorised to issue orders for particular medical devices and the precise descriptions of those devices.

The Regulation will enter into force on 1 January 2023.



Link to the Regulation in the Journal of Laws

Draft regulation on the serious incident report form

The Government Legislation Centre (*Rządowe Centrum Legislacji,* RCL) has published the opinions expressed during the public consultation of the draft Regulation of the Minister of Health on the form for reporting serious incidents related to the use of medical devices. The template form presented in the annex to the draft Regulation has been drawn up in Polish and English to facilitate both the submission and receipt of serious incident reports.

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (*Prezes Urzędu Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*) has asked more than forty organisations to submit their comments on the draft. Among those provided to date, only three contain proposed changes - these were submitted by the Federation of Health Protection Employer Unions (*Federacja Zwiazków Pracodawców Ochrony Zdrowia Porozumienie Zielonogórskie*), the Polish Chamber of Commerce of Medical Devices POLMED (Ogólnopolska Izba Gospodarcza Wyrobów Medycznych POLMED) and the President of the Office for Personal Data Protection (Prezes Urzędu Ochrony Danych Osobowych, UODO). However, these comments are mainly of a technical nature and, in the case of UODO, have already been included in the current version of the draft, which can be found on the RCL website under the link below.

Link to the draft regulation on the government website

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Healthcare

Important change for diagnosticians: publication of the Act on Laboratory Medicine

On 9 November 2022, the Act of 15 September 2022 on Laboratory Medicine was published in the Journal of Laws. The Act, long-awaited by the diagnostic community, sets out the principles and conditions for the practice of laboratory medicine and the profession of laboratory diagnostician, the principles of supervision and control of medical diagnostic laboratories, and the principles of organisation and operation of the professional body of laboratory diagnosticians.

The original bill was drafted by the Minister of Health and first published on the website of the Government Legislation Centre (*Rządowe Centrum Legislacji*, RCL) in July 2020. In the further stages of the legislative process, the Sejm (the lower house of the Polish Parliament) rejected the Senate's amendments to the bill. The Act that finally entered into force after being signed by the President coincides in the most part with the wording proposed by the government. The new Act replaces the Act of 27 July 2001 on Laboratory Diagnostics. In the justification of the new provisions, it was emphasised that although the basic principles of the 2001 act have not changed, its title and much of its content need to be updated to keep pace with the development of knowledge and terminology in the field of laboratory medicine.

One of the new legal solutions introduced by the Act on Laboratory Medicine concerns the practice of the profession of laboratory diagnostician. Among other things, the Act defines who can be authorised to perform laboratory medicine independently, imposes an obligation on diagnosticians to undergo continuing professional development, and grants them up to six working days of paid training leave per year to be used for professional development. In addition, the Act clarifies the provisions regarding the National Council of Laboratory Diagnosticians' supervision of the profession and the rules for conducting visits to laboratories.

Most of the provisions of the Act will enter into force one month after the date of its publication. The full text of the Act is available in the Journal of Laws at the following address.

Link to the Act in the Journal of Laws

Bill amending the Act on the Professions of Physician and Dentist and certain other acts

The government bill amending the Act on the Professions of Physician and Dentist and certain other acts was passed by the *Sejm* (the lower house of the Polish Parliament) on 16 November 2022 and on the following day was forwarded to the President and the Senate.

The bill concerns the optimisation of public spending on healthcare, which is determined annually on the basis of the provisions of the Act on Healthcare Services Financed from Public Funds. In addition, the bill includes regulations on support for the healthcare system after the period of intensified efforts aimed at counteracting and preventing COVID-19.

These objectives are to be achieved, in particular, by transferring the financing of certain areas of the healthcare system from the state budget to the National Health Fund (*Narodowy Fundusz Zdrowia*). This is to apply to highly specialised services, as well as so-called '75 plus' and 'pregnancy plus' medicines (i.e. medicines, foodstuffs for special nutritional use, and medical devices for people over 75 years of age and medicines for pregnant women) and certain medicines and medical devices purchased under the health policy programmes of the Minister of Health. In addition, a new method of financing has been provided for postgraduate internships of physicians and dentists and for the tasks of medical rescue teams.

As a general rule, the Act will apply from 1 January 2023. However, by way of exception, certain provisions will apply from the date the Act is published in the Journal of Laws.

Link to the bill on the government website

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New specialisation in Polish healthcare? A bill is already in the Government Legislation Centre

The Ministry of Health is planning to introduce a new medical field in which it will be possible to obtain the title of specialist. The bill amending the Regulation on specialisations in fields applicable to healthcare proposes the establishment of a specialisation in psychotherapy.

The new specialisation is to be available to people who have obtained a master's degree from the following faculties: medicine, nursing, psychology, pedagogy, sociology, and re-socialisation. According to the legislator, the introduction of this specialisation will result in the healthcare system obtaining highly specialised medical staff to provide services in the field of psychiatric care, as well as increasing the availability of psychotherapy, especially as part of community-based treatment.

The bill is currently at the public consultation stage. The act is expected to enter into force on the day after it is published in the Journal of Laws.

Link to the bill on the government website

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Veterinary issues

New Act on the Animal Identification and Registration System

The Act provides for the alignment of Polish law with European Union regulations, in particular the obligations under Regulation 2016/429 (the so-called 'Animal Health Law'). The aim of the Act is to ensure a consistent system of animal identification and registration.

The scope of the changes being introduced was so significant and extensive that it was decided to repeal the existing Act on the Animal Identification and Registration System in its entirety and replace it with a new piece of legislation. Among other things, the new Act provides for the following:

- the integration of computer databases into new systems (including TRACES),
- notification rules for poultry establishments, including the scope of information to be collected on the poultry housing system (organic, free-range, barn, cage). This information is to be used for further work on improving the keeping of these animals. It can be envisaged that part of this information will be used in connection with possible work on a cage ban - a potential and announced initiative at European level,
- the extension of the obligation to report on the system of keeping animals to people who keep cattle, sheep, goats and pigs,
- rules on data collection concerning equidae,
- means of identification of animals, as well as the replacement of means of identification,
- the abolition of the cattle passport,
- the introduction, from 2026, of an obligation to report animal events only in electronic form.

The Act was signed by the President on 21 November and is expected to enter into force 14 days after its publication.

Link to information about the Act

Draft Regulation of the Minister of Health on the amount of, and manner of determining and paying fees related to the authorisation of a veterinary medicinal product for marketing

The draft Regulation sets fees for activities related to the procedures listed in Regulation 2019/6 (EU Veterinary Medicinal Products Regulation), including some new procedures that are available. It also updates a number of already existing fees. The new fees are set out in an annex to the draft, the highest of which is PLN 92,600 for the submission of an application for a marketing authorisation for a reference veterinary medicinal product in the decentralised procedure, in which Poland acts as the reference country.

The draft also proposes solutions that may reduce the application fee if the responsible entity submits simultaneously more than one application for veterinary medicinal products differing only in formulation or strength.

The Regulation is expected to enter into force on the day following its publication. The draft is currently at the public consultation stage.

Link to the draft regulation on the government website

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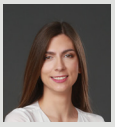

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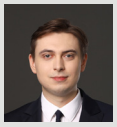

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