Poland | Life Sciences | Legislative changes in September 2022

Below we provide a description of the key legislative changes proposed and introduced in the pharmaceutical sector in September 2022.

Bill amending the Pharmaceutical Law and certain other acts

In the last week of September, the principles of the bill amending the Pharmaceutical Law and certain other acts were published in the list of government legislative works. 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.

Organisational changes in the State Pharmaceutical Inspection

Among the proposed changes is the reorganisation of the State Pharmaceutical Inspection. According to the recently published principles, the bill is to propose changes which will strengthen the position of the Chief Pharmaceutical Inspector as the body supervising the activities of provincial pharmaceutical inspectors. As a result, provincial inspectors are to become employees of the Chief Pharmaceutical Inspectorate, subordinated to the Chief Inspector.

The Chief Pharmaceutical Inspector is also to be entrusted with the supervision of medical diagnostic laboratories. As the authors of the bill point out, the purpose of this change is to ensure proper quality of laboratory activities performed. The issues of control and inspections carried out by the Chief Pharmaceutical Inspector are to be comprehensively regulated in a new chapter of the Pharmaceutical Law.

Additional fee to be imposed on pharmaceutical warehouses and pharmacies

The principles also indicate plans to introduce into the Polish legal order a new model of co-financing the supervision of the manufacture, import, marketing and brokering of medicinal products and the manufacture, import and distribution of active substances. These costs would be borne by pharmaceutical market participants. **In practice, these changes would probably involve pharmacies and pharmaceutical warehouses having to pay an annual fee**, but the details – including the amount of the fee - are not yet known.

Status:

The bill is expected to be ready for publication in the fourth quarter of 2022.

Link to information about the bill on the government website

DLA PIPER

Changes to the quality control of new medicinal products

On 2 September 2022, the Act of 5 August 2022 amending the Act on the Professions of Nurse and Midwife and certain other acts entered into force. This Act, published in the Journal of Laws on 18 August 2022, includes new provisions on the quality control of medicinal products marketed for the first time in Poland, thus clarifying the confusion resulting from the current wording of the Pharmaceutical Law.

The amendment addressed the doubts concerning the correct implementation of the obligation to inform the Chief Pharmaceutical Inspector about medicinal products being placed on the market for the first time in Poland. Some of the phrases in the Pharmaceutical Law have been replaced with more precise ones, and additional, more detailed issues related to the process of conducting quality tests have been clarified.

The new provisions also increase the powers of the Chief Pharmaceutical Inspector to supervise and control the product quality testing process. In order to ensure their effective application, the Chief Inspector has been given the power to impose fines for failing to properly meet the obligation of notifying a product's introduction onto the market (from PLN 10,000 to PLN 100,000) and for failing to submit a product sample with the necessary documentation and materials by the specified deadline (from PLN 50,000 to PLN 300,000). The Act also changes the circumstances in which the Chief Inspector may issue a decision to withdraw a medicinal product introduced for the first time onto the Polish market.

Link to the Act in the Journal of Laws

DLA PIPER

Bill amending the Act on Food and Nutrition Safety

Earlier in September, the principles of the bill amending the Act on Food and Nutrition Safety, including changes in the regulation of dietary supplements, were published in the list of government works. The planned changes are intended to improve supervision over the dynamically developing market of these products, including their advertising and presentation.

The legislator, aiming to protect the health and lives of consumers, proposes more detailed rules on the presentation and advertising of dietary supplements. According to the authors of the bill, in the absence of comprehensive regulation in this area, people who buy or take dietary supplements are currently at risk of being misled about the effects and properties of the available products, and confusing supplements with medicines.

Planned changes to the regulation of dietary supplements

In response to these problems, new rules have been proposed, such as the obligation to introduce a disclaimer during presentation or advertising stating that: „A dietary supplement is a foodstuff intended to supplement the normal diet. A dietary supplement has no medicinal properties." The principles also included a ban on using images of authorities and experts in the field of medicine and health in advertisements, as well as objects and activities that may be associated with healthcare professions. In addition, the target group for advertising supplements is to be limited, excluding children under 12 years of age. Restrictions are also planned for so-called umbrella brands, where the name, labelling or other elements of the supplement resemble those of an existing medicine on the market.

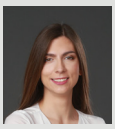
In addition, the proposed amendments are to require the physical separation of medicines and dietary supplements in pharmacies and other places of sale, as well as restrictions on the place and manner of presenting dietary supplements. The bill will also propose using a voluntary mark confirming the quality and safety of a product based on an analysis of its composition. Displaying the mark would be possible after conducting laboratory tests and obtaining an opinion of a scientific body confirming compliance with food and dietary supplement safety requirements (quality certificate). In addition, the bill will clarify the procedures for notifying the Chief Sanitary Inspector about the first marketing of certain foodstuffs and will allow the authorities to impose effective, proportionate and deterrent fines for breaching the requirements arising from the Act on Food and Nutrition Safety.

Status:

The bill is expected to be published in the fourth quarter of 2022.

Link to information about the bill on the government website

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



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

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