



Report

# E-commerce on the pharmaceutical market

*Guide by IQVIA and Rymarz Zdort Maruta, 2024*

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# Introduction

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The pharmaceutical market, which is based on traditional business models, is currently undergoing rapid transformation due to the growing share of e-commerce. The market phenomena and trends observed in the e-pharmacy sector around the world are also reflected in Poland, but they sometimes differ in scale and pace. This report examines the developing online pharmacy market in Poland, presenting its current situation, main directions of development, dynamics and legal conditions. As patients increasingly use the Internet and modern technologies to take care of their health, this sector has the potential to change the way medicines and other pharmaceutical products are available, distributed and used.

Pharmaceutical e-commerce is part of a larger digital transformation that is driving changes in consumer behavior and expectations. Patients, more than ever before, are seeking convenience, accessibility, and personalized shopping experiences. The rise in chronic diseases, combined with an aging population and growing awareness of health and wellness, are causing consumers to seek more effective ways to manage their existing treatment schemes. The ease of price comparison, the discretion and privacy of online transactions, and the growth of telemedicine services are all further driving the use of online pharmacies.

The online pharmacy market is developing much faster than the traditional pharmacy market. This is influenced by various factors, one of the most important of which is the previously mentioned change in patients' expectations and shopping habits. Other factors driving the development of this sector are lower prices, which attracted patients especially during the phase of rapid inflation growth, and new distribution models, which shortened the delivery time and at the same time ensured the safety of medicinal products.

The online pharmacy market differs from the traditional pharmacy model in several aspects. The digital market blurs geographical boundaries, allowing for greater reach and competition. However, it also introduces challenges related to maintaining a secure supply chain, ensuring compliance with regulations and providing professional support to pharmacists in the virtual space. Legal restrictions, the conservative approach of supervisory authorities, the specificity of trading in medicinal products mean that starting or developing a business on the e-commerce market of pharmaceuticals should be preceded by a thorough analysis and taking actions to increase the legal security of the entire undertaking.

Large pharmacy chains in Poland are investing in the development of their e-commerce platforms and are cooperating with technology companies to strengthen their position on the Internet. At the same time, among the key players on the market, one can find online pharmacies belonging to individual pharmacies or small chains that have found their niche and successfully compete with the largest players.

Seeing these phenomena, IQVIA and the Rymarz Zdort Maruta law firm decided to prepare the **Report: e-commerce on the pharmaceutical market 2024**. Our experts analyzed the key trends occurring on the Polish market, showed the most important business models, presented legal obligations and added a practical commentary. We believe that this report will be interesting for a wide range of entrepreneurs already operating on this market and those just planning to enter the pharmaceutical e-commerce market in Poland and will become a kind of road map leading to the development of their business.

## Key changes predicted for the nearest future

Considering the trends and data analyzed and presented in the report, we predict that the following topics will become more important in the coming years:

- all solutions that increase the comfort of shopping for patients.

Starting from the optimization of product delivery and collection processes, shortening the waiting time for an order, through automation, to the development of online platforms offering users much more than just purchasing medicines – entrepreneurs operating on the e-commerce market have already begun the process of change.

- discussions on allowing online sales of prescription drugs.

There are numerous pro-patient arguments in favor of the delivery of prescription drugs, including facilitating patients' access to prescription drugs that are key to therapy, especially in the case of patients

taking medications continuously or long-term, people with mobility problems, or residents of rural areas with lower access to pharmacies. The delivery of prescription drugs could translate into a reduction in the phenomenon of lack of available medicines for patients, increased "adherence" (compliance with the principles of therapy, compliance and application of medical recommendations) and increased innovation in healthcare in Poland. All the more so because Poland has already implemented key reforms from the perspective of the delivery of prescription drugs, i.e. it has launched an e-prescription system and developed the Internet Patient Account (IKP). The infrastructure necessary for remotely purchasing a prescription is largely ready. On the other hand, the delivery of prescription drugs raises concerns among some in the community, especially in the context of ensuring the quality of delivery of such products. Hence the need for an open discussion and the commencement of work on the optimal solution.

- ESG and all activities related to sustainable development, especially in the environmental aspect.



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# Market Overview

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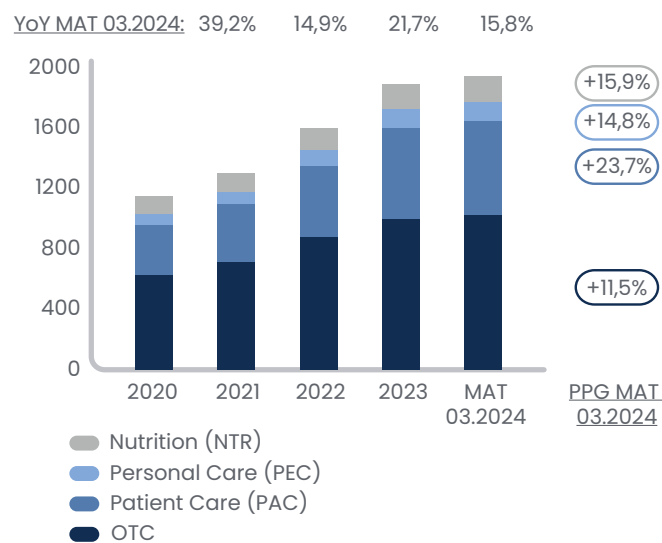
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# Online pharmacy market in Poland

## Value and quantity dynamics of the online pharmacy market

Similarly to other countries, the online pharmacy market in Poland recorded a significantly higher dynamics than sales in the traditional channel. Over the past five years, sales in online pharmacies have been growing double-digitally, and 2020 was a record year in this respect, when the dynamics of sales value in online pharmacies reached 45%. In the following years, the pace of sales in online pharmacies decreased, but was still twice as high as in stationary pharmacies. In 2023, the value of sales in online pharmacies reached PLN 1,892 billion (in retail prices) and was PLN 291 million higher than in 2022. The chart below (FIG. 1) shows the dynamics and value of the online pharmacy market, divided into several categories: products like classic OTC drugs, products from the medical/functional food and dietary supplements group (NTR), personal care products (PEC) and medical care (PAC).

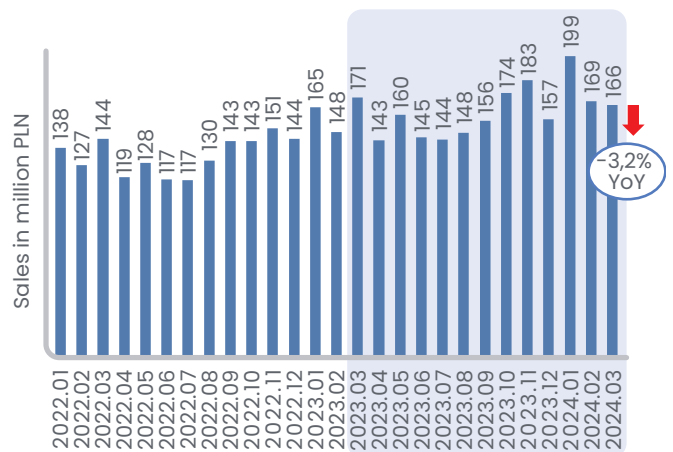
**FIG. 1 Sales in online pharmacies in Poland by category [PLN million]**



Source: IQVIA ePharmacy Tracker, 2024.03

Above the annual bars, the year-on-year dynamics are shown, while on the right-hand side, the dynamics of individual segments in the last analyzed year. In particular months of the year, the dynamics of the growth of the online pharmacy market value ranges from several to several dozen percent. The sales level is somewhat seasonal, and the months with the highest sales value are October and November. Online pharmacies record the lowest sales during the holiday season from June to August. The value of mail-order pharmacies' sales in particular months is presented in the chart below (FIG. 2).

**FIG. 2 Sales in online pharmacies in Poland by month [PLN million]**



Source: IQVIA ePharmacy Tracker, 2024.03

## The Polish market compared to other European markets

Pharmaceutical e-commerce in Europe is diverse and depends on many factors in individual countries, such as the regulatory framework, digital infrastructure, consumer behavior and healthcare systems. Here are some key elements that affect the online pharmacy market in Europe:

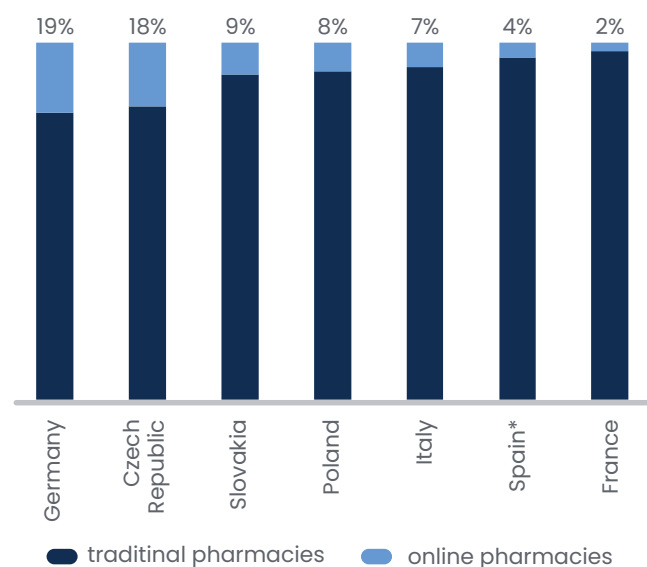
- regulatory environment;
- market maturity;
- digital infrastructure;

1 In the market segment, the term online pharmacy (e-pharmacy) refers to a mail-order pharmacy, excluding click-and-collect sales

- cultural attitudes;
- level of e-prescription implementation;
- reimbursement policy;
- cross-border sales.

The level of development of the online pharmacy market in selected European countries is presented in the graph below (FIG. 3).

**FIG. 3 Share of e-commerce in the pharmacy market 2023**



Źródło: IQVIA CH apteki tradycyjne oraz internetowe,  
\*Hiszpania: zawiera apteki oraz drogerie

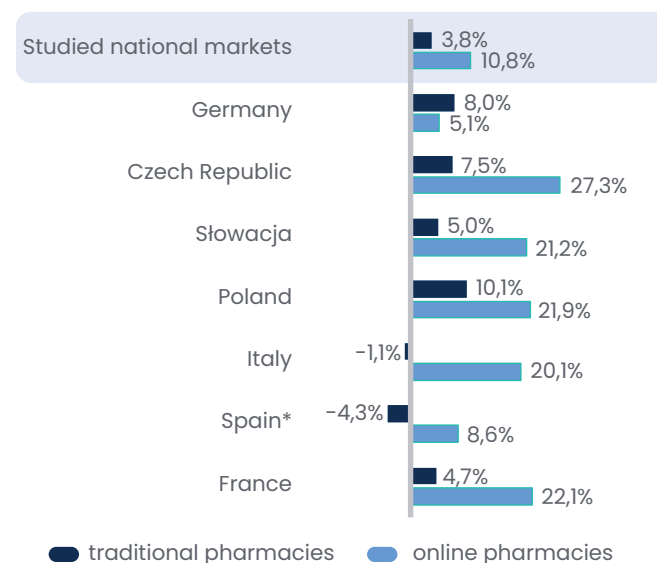
The Polish market is approximately in the middle of the ranking of the e-commerce market share value in total pharmacy sales of CH products (approx. 8%). In the case of selected other European countries, these shares are in the range of 2-19%.

The factors described above also affect the dynamics of the markets, which differ significantly between individual European countries.

In all countries analyzed by IQVIA, sales in mail-order pharmacies grew in 2023, even if sales in stationary pharmacies fell (as experienced in Spain and Italy). Against this background, the Polish market belongs to the group with the highest, double-digit growth. The chart below (FIG. 4) presents the values of the

dynamics of the stationary and online pharmacy market in 2023 in selected European countries.

**FIG. 4 Growth of European e-commerce markets 2023 (€ PUB)**



Source: IQVIA CH traditional and online pharmacies  
\*Spain: includes pharmacies and drugstores.

It is very likely that the rate of growth of sales value in online pharmacies will continue to be higher than in stationary pharmacies in the coming years. The development of technology and the liberalization of regulations regarding the sale of OTC and Rx drugs via the Internet will support these growths.

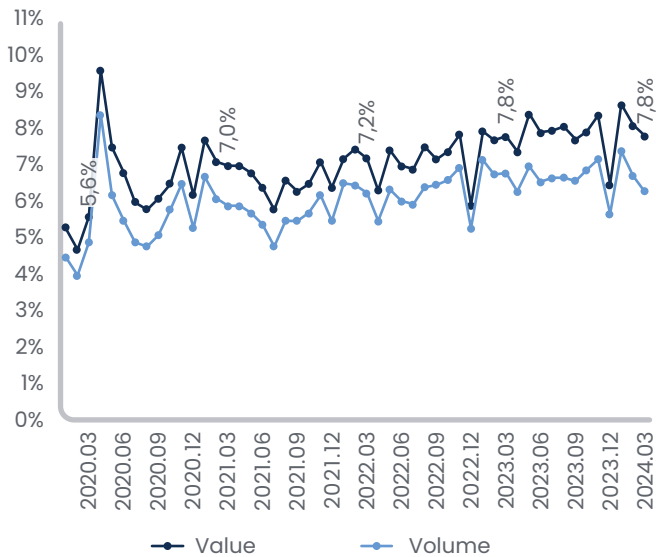
## Share of online pharmacies in the sale of consumer market products<sup>2</sup>

The high dynamics of the online pharmacy market, which has been maintained for years, is reflected in the growth of their share in the sales of the Consumer Health (CH) product category, i.e. OTC drugs, dietary supplements, medical devices sold in pharmacies and cosmetics. At the beginning of 2020, the value share of online pharmacies in the sale of CH products was at the level of 5% of sales on the pharmacy market, at the beginning of the Covid-19 pandemic it increased to almost 10% and then in the second half of 2020 it fell to 6-8%. In the following years, we observed a systematic increase in the share of online pharmacies in the sale of CH

2 Consumer market – Consumer Health, all products sold in pharmacies without a prescription

products. At the beginning of 2024, this share was at the level of 7.5–8.0%. The share of online pharmacies in the sale of OTC products on the pharmacy market is presented below (FIG. 5).

**FIG. 5 Share of e-commerce in CH sales (%)**



Source: IQVIA ePharmacy Tracker and IQVIA Pharmascope, CHC 1-97

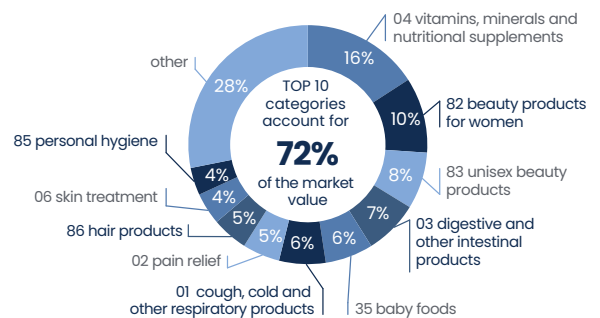
The graph shows repetitive sales cycles in online pharmacies, with characteristic increases in sales and market share in November (Black Friday) and sales declines in December, when stationary pharmacies usually play a greater role, especially those located in shopping malls. As can be seen, the quantitative share of online pharmacies in the pharmaceutical market is slightly lower than the share in value, while since May 2020 their evolution has been almost parallel, with a final value of approx. 6%.

## Differences in sales structure in online and stationary pharmacies

Due to the specificity of e-commerce orders and the need to wait for the delivery of ordered products, the sales structure of the Consumer Health category in online pharmacies differs significantly from that observed in stationary pharmacies. Online pharmacies usually have more to offer than just medicines; one can buy there health supplements, wellness products, personal hygiene products and medical devices.

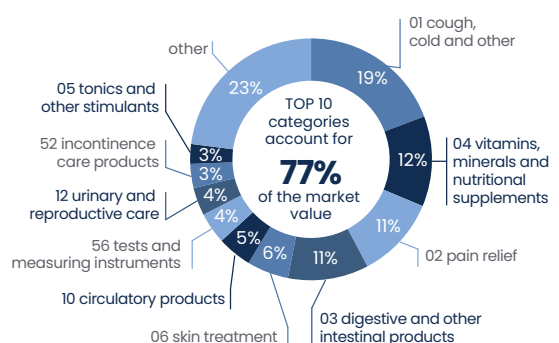
They also offer access to a larger number of pharmaceutical brands and international products, which are not easily available in traditional pharmacies due to space constraints. Online pharmacies also often have competitive prices due to lower overhead costs compared to traditional pharmacies. Additionally, customers who purchase health products or medications they consider sensitive may value the increased privacy and discretion that comes with shopping at online pharmacies. This can be particularly attractive to those who prefer to remain anonymous. These and other elements affect the sales structure at online pharmacies, which is shown below (FIG. 6) compared to the sales structure of assortments in traditional pharmacies (FIG. 7).

**FIG. 6 TOP 10 categories in the online pharmacy market**



Źródło: IQVIA Pharmascope 2023, Cena detaliczna PLN | Rynek CH (1-97) sprzedaż stacjonarna i internetowa | SM

**FIG. 7 TOP 10 categories in the traditional pharmacy market**



Source: IQVIA Pharmascope 2023, Retail price PLN | CH market (1-97) brick-and-mortar and online sales | SM



The largest category in terms of sales value in traditional pharmacies, i.e. "Cold and Flu", is only sixth in the ranking of importance categories by sales value in online pharmacies. It includes medicines and products for minor ailments that the patient wants to buy right away at the nearest pharmacy, instead of waiting a few days for their delivery. In online pharmacies, the first three places in the category ranking are occupied by product groups whose purchases can be planned and which are not needed by patients immediately: vitamins and minerals, cosmetics for women and other beauty-related products. Products from the categories of children's food, hair and skin cosmetics, and intimate hygiene products are also more popular in online pharmacies.

### Key players and balance of power in the online pharmacy market in Poland

The e-commerce market, thanks to its specificity, offers pharmacies opportunities and scale of operations that are not limited geographically. As a result, individual pharmacies can achieve several times higher sales in e-commerce than in the traditional part of their business, and pharmacy chains can also reach those regions where their traditional branches are not located. These opportunities attract many market participants who decide to start mail order sales. As a result, this market in Poland is still relatively fragmented, although over the last few years a group of online pharmacies has emerged that maintain leading positions. The largest players on the market include gemini.pl and aptekamelissa.pl, which for several years have been in first and second place, respectively, in the ranking of online pharmacies in terms of sales value. The position of the remaining entities in the ranking is subject to frequent and quite significant fluctuations. The alphabetical list of 10 mail order pharmacies with the highest sales value is presented in the table (TAB. 1).

**TAB. 1 TOP 10 online pharmacies in 2023\***

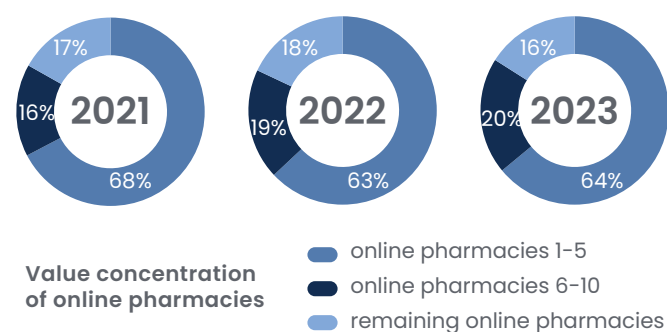
1	a-manada.pl	6	drmax.pl
2	apteka-melissa.pl	7	gemini.pl
3	aptekaolmed.pl	8	hebe.pl
4	aptekarosa.pl	9	superpharm.pl
5	doz.pl	10	wapteka.pl

*Źródło: IQVIA ePharmacy Tracker Ranking total sprzedaż w 2023 | Apteki uporządkowane są wg. kolejności alfabetycznej*

It is also worth noting that the high dynamics and rapidly growing value of the online pharmacy market during the Covid-19 pandemic attracted new players. As a result, on the one hand, the number of online pharmacy websites increased, and on the other, their concentration decreased. The top five largest online pharmacies in 2021 controlled 68% of this market, and a year later it was only 63%. At that time, the second five mail-order pharmacies were developing – their share increased from 16% in 2021 to 19% in 2022.

The growth of competition in the online pharmacy market slowed down in 2023, and fewer new players also appeared on the market, which led to an increase in market concentration and shares: to 64% for the top five online pharmacies and to 20% for the second five, respectively. Changes in the concentration of online pharmacies in Poland over the last 3 years are presented in the graphs below (FIG. 8).

**FIG. 8 Changes in concentration of online pharmacies in Poland over the last 3 years**



In the context of online sales, it is also worth noting click-and-collect sales, i.e. ordering products in the online channel and then collecting orders directly at the pharmacy. This formula allows patients to reserve and collect Rx medications (in the pharmacy, the prescription must be shown to the pharmacist). In the case of this channel, the ranking of sales values in individual online pharmacies / domains is different than in the case of online sales with delivery and it was not included in the analytical part of the report.

## Key market trends in the online pharmacy market in Poland

Following and understanding key trends in the e-commerce pharmaceutical market is particularly important for entities that want to take advantage of the opportunities offered by the digital transformation of the pharmaceutical industry. In the online pharmacy market, we observe most of the trends noticeable in the entire pharmaceutical market in over-the-counter products, but their intensity may be different than in the case of the stationary market. There are also trends specific only to the e-commerce market. Among these markets is the mentioned click-and-collect area, also growing rapidly on the Polish market.

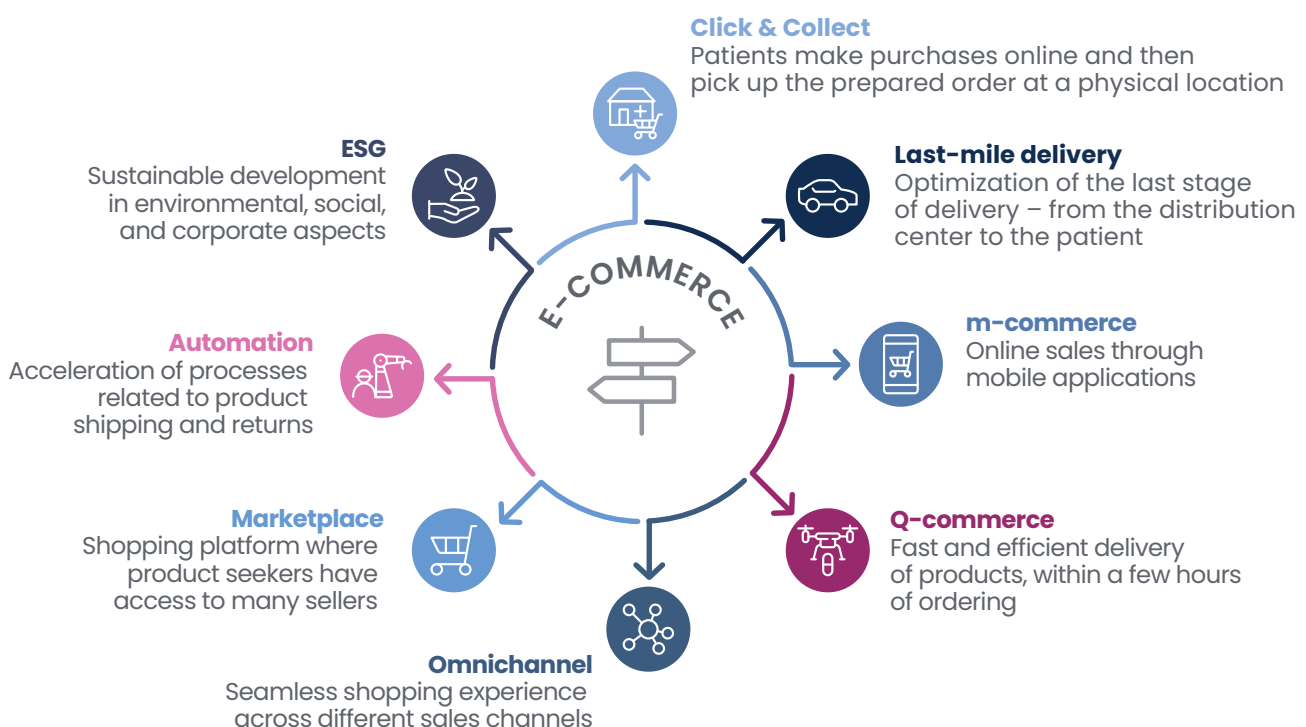
Other trends observed on the Polish market, specific to the e-commerce market, include:

- last mile logistics (optimization of direct delivery to the patient);
- m-commerce (mobile sales);
- Q-commerce (quick sales);
- omnichannel (multi-channel sales);
- marketplace (use of a shopping platform to sell individual pharmacies).

In the common scope of the e-commerce market and the stationary pharmacy market, we can mention the growing automation of pharmacies and pharmaceutical wholesalers, including the use of warehouse robots to streamline order logistics and improve packaging quality (reduced number of errors, etc.).

Across the entire market of medicinal products, there is also a noticeable tendency, for now mainly in Western Europe, to increase the components of sustainable development in the production and trade of products - in the field of pharmaceutical products, these include, among others, reducing packaging and the consumption of materials for

**FIG. 9 8 trends in the e-commerce of pharmacies in Poland**



their production, optimizing transport and energy costs, and numerous other activities.

A full list of the presented trends is presented in the graphic below (FIG. 9).

The scope and strength of the impact of the above trends on the online pharmacy market in Poland depend on many factors, such as: technological progress, changes in shopping habits and the needs of e-patients, but above all on regulatory changes. The trends presented in Figure 9 are at various stages of development on the Polish market, and the potential for their further development

towards more advanced markets in Europe is sometimes limited by legal barriers.

Changes to the legal environment of e-commerce, and in particular the admission of solutions improving the convenience, safety and benefits of patients, may significantly change the dynamics, structure and prospects of the online pharmacy market in Poland. Hence, when analyzing the direction of legal changes in the field of online pharmacies, it is necessary to analyze the potential effects of these changes on all market participants.



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# Legal part

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# The definition of an online pharmacy. The range of products permitted to be sold over the internet

What is an online pharmacy from a legal point of view? How does it differ from a traditional (physical) pharmacy? What legal requirements should be met by a business entity intending to operate an online pharmacy? What should be kept in mind when running this kind of business? These and other questions are addressed below.

## What is an online pharmacy?

An online pharmacy (also called an e-pharmacy) is in fact a standard pharmacy which, in addition to its on-site activities, conducts mail order sales of over-the-counter (OTC) medicinal products, excluding products the dispensing of which is restricted by the age of the patient. Pharmacy points (*punkty apteczne*) also have the right to conduct mail order sales of OTC medicines within the scope of their product range.



### Rules for obtaining a licence to operate a community pharmacy

If you want to operate an online pharmacy, you must first have a licence to operate an on-site pharmacy.

The formal process of starting mail order operations is in itself not difficult (only a notification to the Pharmaceutical Inspectorate is required).

The applicable legislation does, however, provide for a number of restrictions and requirements for opening an on-site pharmacy. Currently, the Pharmaceutical Law only allows pharmacists or registered partnerships / professional partnerships of pharmacists to open a community pharmacy, and only in selected locations (that meet demographic and geographic criteria).

In addition, the possibility of acquiring a company that owns existing pharmacies was significantly restricted in 2023.

For this reason, the number of on-site pharmacies in Poland has been declining year on year.

More flexible rules apply to the opening of pharmacy points, which also have the ability to conduct online sales; their operation, however, has been limited to rural areas only, as long as there is no pharmacy in the village in question.

As a result, entry into the e-commerce market for medicines in Poland has now been significantly restricted.

## What range of products can an online pharmacy sell?

- OTC medicines, excluding products the dispensing of which is restricted by the age of the patient;
- medical devices;
- foodstuffs for particular nutritional uses;
- dietary supplements;
- what are referred to as “dermocosmetics”, i.e. cosmetics not intended to beautify or provide fragrance;
- hygiene products;
- baby and sick care items,
- foodstuffs formulated with pharmacopoeial natural ingredients of plant origin;
- medical disinfectants;
- biocidal products for human hygiene and repellents or attractants for direct or indirect human hygiene use.

The above list is a closed one, and going beyond its scope (both in terms of on-site and mail order sales) may be challenged by the Pharmaceutical Inspectorate.

## Products that an online pharmacy cannot sell via mail order

- prescription-only medicinal products;
- medicinal products the dispensing of which is restricted by the age of the patient;
- other products outside the list of permitted pharmacy stock (e.g., beautification or fragrance cosmetics).



### Having doubts about the status of a product?

Even though an exhaustive list of the types of products that a pharmacy may sell has been published, in practice there are many uncertainties as to whether specific products (e.g., certain cosmetics) constitute permitted pharmacy stock.

If you have concerns about a particular product and are wondering if it can be sold in an e-pharmacy, please consult your legal advisor.



### Can prescription medicines be bought online?

Wondering why online pharmacy websites show prescription-only products (marked "Rx") as available?

These are products that you can reserve online and pick up at an on-site pharmacy. See the "Click & Collect" section below.

## Online pharmacies: how to open an e pharmacy

### How to set up an online pharmacy?

**A pharmacy operator who plans to start mail order sales of medicines is required, 14 days before commencing such sales, to provide the competent regional pharmaceutical inspector with the following information:**

- the business name and address and the place of residence, or the business name and address and the registered seat of the entity for which the license to operate a pharmacy or a pharmacy point has been issued - provided that if the pharmacy owner is a self-employed individual (a sole trader), the address of the actual place of business should be given instead (if different from the address and the place of residence);
- the address of the pharmacy or pharmacy point;
- the name of the pharmacy or pharmacy point, if one is given;
- the address of the website through which the pharmacy or pharmacy point will conduct mail order sales of medicinal products;
- the telephone number, fax number and email address; and
- the date of commencement of pharmacy operations.

### Requirements that must be met by the premises out of which an online pharmacy is operated

The standard premises of an on-site pharmacy or a pharmacy point conducting mail order sales of medicinal products must additionally be fitted with a space dedicated to the preparation of medicinal products for shipment, which should be partitioned off from the dispensing room, the storage room or the receiving bay in such a way as to enable the pharmacy staff to properly handle the stock.

In addition, the place designated for the preparation of medicines for shipment must be equipped with:

- a table for preparing shipments;
- a cabinet or rack for storing external packaging materials; and
- a platform or rack for storing prepared shipments.

### **Information that should be placed on the website of an online pharmacy**

The law provides for a number of information obligations related to an e-pharmacy's website. The key one is to make an order form easily available to patients:

- that contains data identifying the facility: name, address, telephone number of the facility receiving the order and the number of its valid permit to operate;
- that allows the purchaser to fill in their data: name and surname (or business name), address, email address and telephone number,
- that makes it possible to add the recipient's data: name and surname (or business name), address, and telephone number, if different from that of the purchaser;
- that contains data on the ordered medicinal product: name, dose, package size, pharmaceutical form, and the number of packages; and
- that contains the order number, order date, and the name of the person accepting the order.

The provision of the above data should be a condition for the order to be processed; however often the data of the purchaser and the recipient are the same.

Regardless of the above requirement for the order form to contain the operator's license number, a link to the license held in pdf format should be placed on the website of the online pharmacy where medicinal products are offered for mail order.

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3 Data as at 4 June 2024

In addition, an online pharmacy website should include:

- contact details of the relevant regional pharmaceutical inspectorate, including at least:
  - » the name of the relevant office,
  - » its office address,
  - » its email address,
  - » its phone and/or fax number;
- a clearly visible common EU logo containing a hyperlink to the entry in the list of pharmacies in the Center for e-Health (CeZ), where information is available about the pharmacy and its registration with the Regional Pharmaceutical Inspectorate.



[LOGO: click to verify whether this website operates in compliance with the law]

- a hyperlink to the Public Information Bulletin of the State Pharmaceutical Inspection Authority (GIF), where you can find information on the regulations governing mail order sales in Poland, the common logo, and the risks associated with the purchase of medicinal products acquired illegally via the internet; and
- a hyperlink to the National Registry of Pharmacies.

### **Is the list of online pharmacies publicly available?**

Information on online pharmacies is included in the National Register of Permits to Operate Community Pharmacies and Pharmacy Outlets and the Register of Granted Permits to Operate Hospital and In-House Pharmacies. Currently, 333 on-site pharmacies in Poland have declared their intention to sell medicines by mail order<sup>3</sup>.



Do you want to check how many online pharmacies are operating in a particular locality / region?

Click here: [Register of Pharmacies \(ezdrowie.gov.pl\)](https://www.ezdrowie.gov.pl).

## Online pharmacies: how to operate an e pharmacy

### What to keep in mind when operating an online pharmacy?

Online pharmacy operators must comply with the applicable requirements of the law, including the Pharmaceutical Law<sup>4</sup> and the Regulation of the Minister of Health on the mail order sale of medicinal products<sup>5</sup> (the "Regulation") in terms of, among other things:

- **the quality and safety of the products** – mail order sales must take place under conditions that ensure the quality of medicinal products and the safety of their use;
- **proper packaging and transport of medicines** – in such a way as to preserve their quality and integrity;
- **keeping of records** of a given order for a period of at least three years from the end of the calendar year in which the order was completed;
- **designation of the pharmacist responsible** for the correct fulfilment of mail order sales of medicinal products and for ensuring that patients have access to a pharmacist;
- **handling product returns** in the situations provided for by law.

4 Pharmaceutical Law of 6 September 2001 (consolidated text: Journal of Laws 2024, item 686, as amended).

5 Regulation of the Minister of Health of 26 March 2015 on mail order sales of medicinal products (Journal of Laws, item 481).



### Returns of products purchased in a pharmacy in the context of consumer rights

Consumers have become accustomed to being able to cancel distance contracts and to having ample rights to return goods.

However, when it comes to purchasing from an online pharmacy, the general rules are somewhat different. Consumers do not have the right of cancellation or return for three categories of goods: medicinal products, foodstuffs for particular nutritional uses, and medical devices. Only exceptionally, the return of medicines and medical devices is allowed in the case of a quality defect, wrong delivery or a product being counterfeit.

It is interesting to note that for other categories of goods sold in online pharmacies, the standard right of withdrawal within 14 days remains valid.



### Sale of medicines through a mobile app

The following forms of placing an order in an online pharmacy are currently permitted: at the pharmacy's place of business, by telephone, by fax, by email, and by filling in a form on the pharmacy's website.

However, the list of ordering methods stipulated in the Regulation does not include the use of mobile applications. It seems that the time has come to update that catalogue to include sales via mobile apps. Otherwise, customers ordering products through smartphones will continue to be deprived of a convenient way to purchase medicines.



## How to package medicinal products sold by mail order?

Medicinal products sold through e-commerce channels:

- must be packaged in such a way as to preserve their quality and integrity,
- and furthermore:
- the outer packaging of the consignment must carry a securely attached label showing: the stamp of the facility (i.e. the pharmacy), the order number, details of the consignee, details of the transport arrangements, and a telephone number for contacting the pharmacist.



### How to secure the parcel?

In practice, online pharmacies secure shipments using polybags and standard shipping cartons.

## The transport conditions for medicines that an online pharmacy must provide

Medicinal products should be transported in dedicated compartments in means of transport that ensure:

- that medicinal products are protected against organic contamination and mechanical damage as well as against microorganisms and pests;
- conditions preventing the mixing of medicinal products, including their mixing with other goods and the contamination of medicinal products;
- conditions preventing unauthorised access to medicinal products;
- that the temperature conditions are maintained as laid down for this medicinal product by the marketing authorisation holder or the relevant pharmacopoeia.



## Transport of medicines – practical problems

In practice, the biggest challenge is the aforementioned obligation to maintain the temperature conditions prescribed for the medicine by the marketing authorisation holder or the relevant pharmacopoeia.

Pharmacies employ a variety of operational systems to comply with these transport obligations.

Some online pharmacies work with transport companies that specialise in temperature-controlled product delivery. Others negotiate temperature control or additional ways of securing consignments of medicines when establishing cooperation with standard courier companies. Some leave the final choice of transport company to the patient, informing them of the benefits of delivery by specialised transport.

We recommend that legal counsel be consulted on the content of agreements entered into by pharmacy operators with courier companies.



## Delivery to parcel lockers.

Automated collection points called parcel lockers are a popular delivery method for products sold online. Currently, this option is not available on the Polish pharmacy market due to the rigorous approach of the Pharmaceutical Inspectorate and the lack of a clear legal basis to implement this delivery method.

With regard to the possibility of collecting pharmacy parcels at pick-up points (grocery shops, drugstores, courier shops), one should first verify the content of the agreement with such an entity and the conditions for storing pharmacy parcels.

## Can an online pharmacy be operated without the involvement of a pharmacist?

No. Quite apart from the fact that currently only pharmacists can open and run pharmacies, a business entity selling medicines by mail order through an online pharmacy is required to:

- **appoint a pharmacist** with a valid licence to practise or **a pharmacy technician** with two years' full-time practice in a pharmacy to act as the person responsible for the correct performance of mail order sales of medicinal products.
- **ensure that patients are able to telephone** such appointed pharmacist or pharmacy technician during pharmacy working hours and for two hours after the agreed time of delivery with inquiries concerning the quality and safety of the medicinal product sold by mail order.

The designated pharmacist or pharmacy technician must, as part of their duties, check that the preparation of the shipment and the conditions of transport of the medicinal products guarantee that:

- the medicinal product can be identified;
- the establishment dispatching the medicinal product, the recipient, and the place of delivery of the medicinal product can be identified;
- medicinal products are protected from being mixed with other products;
- medicinal products are protected from contamination, mechanical damage or theft;
- medicinal products are protected from the harmful effects of heat, cold, light and moisture and other adverse agents;
- the temperature specified by the marketing authorisation holder or the relevant pharmacopoeia is maintained;
- there are safeguards against the marketing of counterfeit medicinal products.

6 Following a challenge to the scope of the current ban on pharmacy advertising in proceedings before the Court of Justice of the European Union, a revision might be imminent. At the time this guide was published, the Ministry of Health had not yet made detailed proposals for an amendment.

## Is the operation of an online pharmacy subject to supervision by the Pharmaceutical Inspectorate?

Yes. The Pharmaceutical Inspectorate can verify things such as:

- whether the website of the online pharmacy is in full compliance with the relevant information obligations;
- whether medicines sold online are correctly packaged and transported;
- the rules for accepting and processing returns of medicinal products;
- marketing activities in relation to advertising for medicinal products via an online pharmacy website; and;
- whether the pharmacy operator complies with the statutory ban on advertising pharmacies<sup>6</sup> and their activities.



### Ban on pharmacy advertising

Polish Pharmaceutical Law states that advertising of pharmacies and pharmacy outlets as well as their activities is prohibited. The legislature made a single explicit exception and permitted the publication of information about the location and working hours of a pharmacy or a pharmacy outlet. The ban applies to all those engaging in advertising activities, not only pharmacy operators. A fine of up to PLN 50,000 may be imposed, together with a cease and desist order, by the competent regional pharmaceutical inspector on anyone who violates the above ban.

With regard to online activities, the Pharmaceutical Inspectorate may verify, for example:

- the contents of an e-pharmacy's newsletter;
- the ways in which the online pharmacy is being promoted (information on promotions or free deliveries of medicines);

- The ways in which customers are encouraged to make purchases;
- the online pharmacy's cooperation with other entities (e.g. search engines presenting the availability of medicinal products or price comparison services).

and assess them for compliance with the law, including in terms of the statutory ban on pharmacy advertising.

It should be noted that the ban on pharmacy advertising is interpreted restrictively by both the Pharmaceutical Inspectorate and the administrative courts, which uniformly accept that any action intended to induce potential customers to purchase specific goods or use specific services constitutes advertising

(judgment of the Supreme Administrative Court of 13 April 2021, ref. II GSK 699/18). This makes it possible to classify most activities relating to pharmacies as 'pharmacy advertising'.

Although, in practice, the Pharmaceutical Inspectorate focuses on physical types of advertising media (outdoor, print, etc.) rather than online advertising, it has, however, challenged the posting of information on a medicinal product's (the manufacturer's) website about the option of purchasing that product from a specific online pharmacy, together with a hyperlink to that pharmacy's website, or posts on the pharmacy's social media.



## SEO

The Chief Pharmaceutical Inspector found that a search engine positioning service for an online pharmacy does not violate the ban on pharmacy advertising, as long as such activities are not accompanied by content that additionally encourages purchases from that pharmacy.



## Advertising of medicines on an online pharmacy's website

Current legislation does not contain specific restrictions on where medicinal products may be advertised. Such advertising may therefore appear on the websites of pharmacies.

However, advertising of a medicinal product can only be carried out **by or on behalf of the marketing authorisation holder**. Close cooperation with manufacturers should therefore be ensured.

With regard to prescription medicines, there is an unconditional ban on their advertising to the public.

Please note, however, that information on animal or human health or diseases is not considered to constitute advertising of medicinal products, provided that it does not refer even indirectly to medicinal products.

## Penalties for breaches of mail order legislation

The commencement of mail order sales by an entity that does not have the required licence to operate a pharmacy or a pharmacy point carries the risk of a fine, restriction of liberty, or imprisonment of up to two years.

However, if an operator holds a licence to operate a pharmacy or a pharmacy point, but merely fails to notify its intention to sell by mail order to the Pharmaceutical Inspectorate, it is subject to a fine.

In addition, an entity that conducts mail order sales of medicinal products, the dispensing of which is restricted by the age of the patient, is subject to a fine of up to PLN 500,000.

## E-pharmacies on marketplace platforms

Within the framework of online sales, as in the case of in-store sales, it is common for multiple competing sellers to merge into a single online space. From the perspective of a trader, especially an individual seller with a limited marketing budget, being part of a wider sales platform enables you to reach a potentially unlimited customer base. From a user's perspective, marketplace platforms provide the option for easy comparison of listings from multiple traders and the ability to compile orders containing products that may not be available from a single retailer.

The Polish e-commerce market is characterised by the existence of one local marketplace platform with a very strong market position that attracts the traffic of almost two-thirds of Polish internet users<sup>7</sup>. Inevitably, the question arose whether online pharmacies could legally cooperate with marketplace platforms.

The issue raised concerns among regulatory authorities due to the wording of two pieces of existing legislation: the statutory definition of mail order sales of medicinal products implying that medicines are sold directly from pharmacy to patients and the requirement that an online pharmacy order form be displayed directly on a pharmacy's website.

Consequently, in 2018, the Supreme Administrative Court<sup>8</sup>, in a case concerning the sale of medicines by an online pharmacy through an auction portal, held that such sales violate the aforementioned rules stipulated by the Pharmaceutical Law. In the opinion of the court, the legislature, by allowing community pharmacies to conduct mail order sales of OTC

medicinal products, precluded the possibility of intermediation in the conclusion of contracts for the sale of medicines. Consequently, online sales models in which pharmacies sell medicines via auction/marketplace portals were held to be incompliant with the law.

There was a shift in the approach of the courts in 2022 brought about by a ruling by the Regional Administrative Court in Warsaw<sup>9</sup>. The court noted a change in Allegro.pl's business model and held that the requirement to sell medicines directly via a pharmacy's website is also met if it is a website provided by a marketplace/auction portal, as long as it serves as a standalone website (i.e. it has a unique URL). In the court's view:

*it should be pointed out that the "website of the facility" is both a website as defined by the authority, i.e. provided by a 'hosting company', as well as a page hosted by a service provider such as Allegro.pl.*

The judgment of the Regional Administrative Court in Warsaw is not yet final and non-appealable. The position of the Supreme Administrative Court in this case will be crucial for the future functioning of pharmacies on marketplace platforms.

Currently, most regional pharmaceutical inspectors accept pharmacy websites set up using a marketplace-specific domain, but in several regions this sales model is still considered questionable.

7 <https://www.portalspozywczy.pl/handel/wiadomosci/allegro-liderem-na-rynku-e-commerce-chociaz-vinted-przyciaga-na-dluzej,234871.html>

8 Judgment of the Supreme Administrative Court of 27 February 2018 (ref. II GSK 1269/16). The decision of the Supreme Administrative Court is the final instance in the case in question

9 Judgment of the Regional Administrative Court in Warsaw of 12 October 2022 (ref. VSA/Wa 1244/22)



### Online pharmacies in price comparison engines

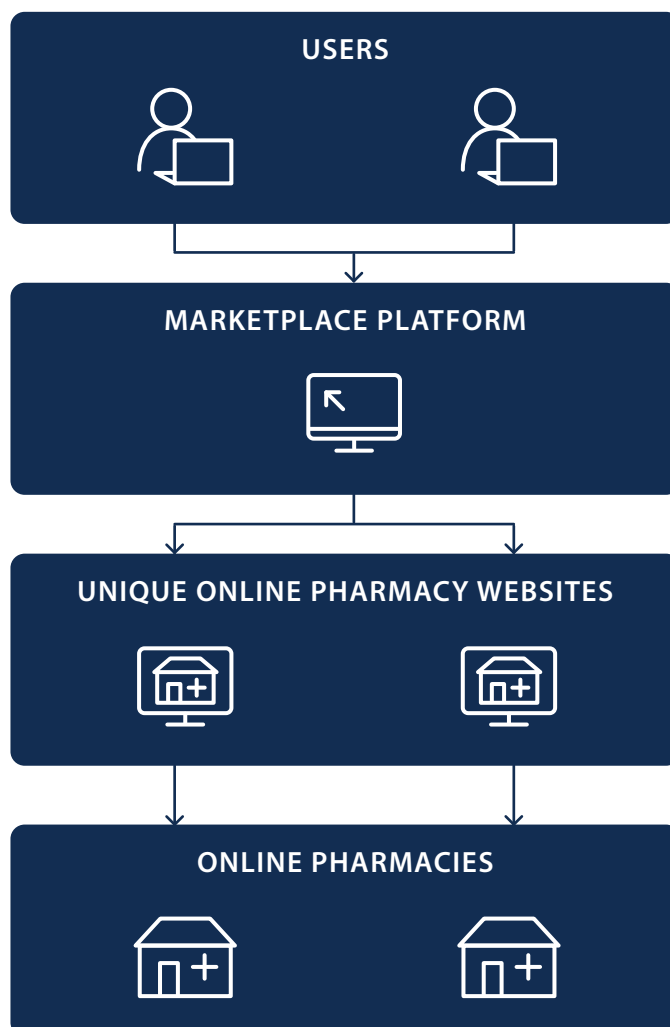
The Supreme Administrative Court also looked at the issue of online pharmacies being featured on price comparison sites, i.e. sites that bring together offers from different retailers in order to allow users to compare prices of the same products in different outlets.

The court found that the featuring of pharmacies on price comparison sites breached the pharmacy advertising ban, as the function of filtering offers by price amounts to encouraging the user to buy a product in a particular pharmacy because it has the lowest price. Similar negative decisions were also made in several proceedings conducted by bodies of the Pharmaceutical Inspectorate.

In practice, however, pharmacies continue to be featured on popular price comparison engines and this practice is not frequently challenged.

Judgment of the Supreme Administration Court of 22 October 2021, ref. II GSK 971/21.

FIG. 10 Diagram of cooperation between online pharmacies and the marketplace evaluated by the court as permissible



Based on the standard developed in case law for cooperation between online pharmacies and marketplace platforms, traffic between different websites should be such that the finalisation of an order by a user always takes place on an online pharmacy's unique website:

We foresee a further increase in the relevance of marketplace platforms for the online sale of medicines and the development of online platforms dedicated to the health & beauty market, bringing together online pharmacies and e-pharmacies.



### Does Polish Pharmaceutical Law properly implement the Pharmaceutical Directive?

The permissibility of distance selling of OTC medicines by online pharmacies has been regulated at European level. The Pharmaceuticals Directive requires Member States to allow mail order sales of OTC medicines.

The rules of cooperation between online pharmacies with marketplace platforms have also been brought to the attention of the Court of Justice of the European

of the European Union (Judgment of 29 February 2024, C-606/21) in a case concerning the French website Doctipharma, an association of individual online pharmacies.

In the judgment, the Court ruled that if the service provider concerned (the platform), in providing a service different from the sale itself, merely enables a connection to be made between sellers and customers, Member States may not prohibit that service on the grounds that the platform in question is involved in the electronic trading of medicinal products.

Therefore, the Court confirmed that cooperation between online pharmacies and marketplace platforms is permissible by recognising this as an information society service.

The question remains whether the current Polish regulations restricting the sale of medicines through marketplace platforms and forcing the sale of medicines to be made directly through a pharmacy's website do not violate the European standard for access to information society services.

In our view, the Court of Justice ruling will make a compelling case for the development of online sales of medicines using intermediary websites.

## When online pharmacy is not enough – expanding a product portfolio

A growing trend in the pharmaceutical e-commerce market in recent years is the expansion of a product portfolio beyond the catalogue of pharmacy-only goods. In fact, we

would like to remind you that the Pharmaceutical Law provides for a closed-end catalogue of products to be sold in pharmacies. The catalogue does not list, among others, cosmetic products used for beautifying purposes (colour cosmetics), perfumes, glasses, cleaning products, sports accessories, etc.

A pharmacy operator planning to expand the portfolio of products offered to customers therefore needs an e-commerce operating model that allows for the combination of an online pharmacy and other business activities such as a drugstore or optician. In principle, two models of cooperation are possible:

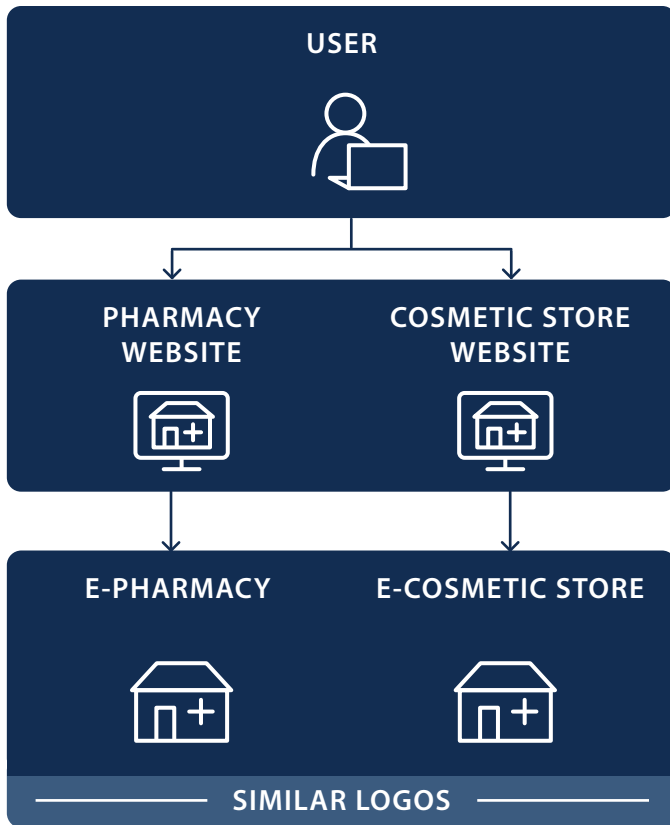
**FIG. 11 Product portfolio expansion models**



In the umbrella branding model, the pharmacy operator runs several separate sales channels, combining them under a similar logo. For example, with a pharmacy brand, the pharmacy operator develops a cosmetic store, an optical business or a health education. In practice, each of these activities has a separate website and a separate shopping cart for the user. Separate sales channels allow for the free expansion of the offered goods, but on the other hand, they limit the synergy effect and are a hindrance from a user experience perspective. The lack of a common product search engine prevents users from purchasing different product categories in a single visit to a website.

The umbrella branding model (i.e. separate websites operating under a similar brand) is as follows:

FIG. 12 Umbrella branding model



### Umbrella branding and the ban on pharmacy advertising

Operating businesses other than pharmacies, such as e-cosmetic store or opticians, has not been banned from advertising them. This means that e-cosmetic stores have the right both to run marketing campaigns promoting their brand and to run promotional campaigns for their customers.

In the case of umbrella branding, i.e. operating under a similar banner, the situation becomes more complicated. As noted by the Supreme Administrative Court (Polish: *Naczelny Sąd Administracyjny, NSA*) in its judgment of 24 March 2023 (ref. II GSK 1120/21), the similarity of logotypes may produce in the recipient of an advertisement an association between the advertised product and a specific pharmacy brand. Therefore, it is possible that activities

promoting other types of activities will be questioned if they indirectly translate into advertising of the pharmacy itself (associative advertising).

In practice, as long as the pharmacy logo is provided with elements differentiating it from the cosmetic store logo and the marketing action does not concern pharmacy products/services, the marketing material should not be questioned, as confirmed by a number of administrative court decisions in recent years.

The second solution found on the market is the model of functioning of a single sales platform allowing several business activities to be carried out within one website. This model is similar to marketplace platforms, but, as a rule, it is limited to selected sellers operating under a similar logo / within the same capital group.

From the user's perspective, the main difference is that they focus on a single website, and use a single product search engine and a common product category tree. At the same time, there can be several independent retailers / services within the same platform, such as an online pharmacy, e-cosmetic store, optician, health guide, telemedicine consultation, C&C model for prescription medicines, etc. Once the transaction is finalised, the customer receives products from different sellers and receives several separate receipts.

FIG. 13 One sales platform model



\* The order is completed on the (unique) pharmacy website, see notes about the marketplace

### Benefits:

- going beyond the closed-end catalogue of products authorised for sale in a pharmacy;
- from the perspective of the user – a common product search engine, an expanded category tree;
- greater advertising possibilities of the platform with regard to non-pharmacy products; and
- the sales platform is easier to combine with other functionalities developed on the health & beauty market, for example: mobile applications, telemedicine, and remote consultations with pharmacists.

### Legal challenges:



#### Sales platform vs Google Ads

Google blocks the use of its advertising tools in relation to online pharmacies. A sales platform combining a pharmacy and cosmetic goods may use more advertising tools with regard to the cosmetic assortment.



#### Can an e-pharmacy's website be considered its location?

As we recall, an exception was made to the broad ban on pharmacy advertising for information on the location and opening hours of a pharmacy or pharmacy outlet. The question therefore arises – in addition to the physical address of the pharmacy, can the information material also include the e-pharmacy's website address (virtual 'address')? Although this issue is not directly regulated in the Polish Pharmaceutical Law, we can see arguments for the permissibility of such an action.

When deciding to develop a common sales platform that will include a pharmacy, it is important to bear in mind the need to:

- adapt marketing campaigns promoting the platform and the risk of associative advertising;
- provide a separate pharmacy website on which the purchase of the pharmacy-related order will be completed; and
- clearly inform the user about the portal they are on, from whom they will complete the purchase of the products, to whom they will have to report complaints, etc. The process should be transparent enough so that, from a consumer perspective, there are no doubts as to whether it is the pharmacy itself, and not the platform or the e-cosmetic store, that is selling the mail order medicines.



#### Legal challenges

From a legal perspective, in order to launch a sales platform, you need to be precise in communication with users, provide for appropriate labelling of products on the website, introduce rules and regulations for the sales activities of individual shops within the platform, use separate tax treatment of sales and, finally, take care of the security of patient data.



**Prohibition of the transfer of individual patient identifiable data**

Under the Pharmaceutical Law, the Pharmaceutical Inspector may withdraw a pharmacy licence issued to a pharmacy that has transferred data that allows the identification of an individual patient, doctor or healthcare provider to unauthorised entities.

Therefore, when designing an e-commerce model using an online pharmacy, it is crucial to foresee the appropriate direction of data transfer. This is because the pharmacy can receive user data from another entity, but cannot transfer it externally.

In models where online pharmacies collaborate with external platforms, additional security of pharmacy data, such as a Chinese wall or encryption, is often used.

## Click & Collect – you order online and pick up in-store

The C&C model differs from mail order in terms of:

- the point of time when the pharmacy enters into a sales contract with the patient; and
- the need for the patient to physically visit the pharmacy.

Only the order is placed online – the payment is received and sale is completed directly at the pharmacy.

FIG. 14 C&C model scheme



In comparison: in the **mail order** model, the payment is received and the sale is completed online, and delivery is made to the address provided by the user:

FIG. 15 Mail order scheme



The C&C model represents a hybrid solution combining a standard in-store sale (on the premises of a pharmacy) and an online sale. From the perspective of a pharmacy owner, this model has two main advantages:

- the user is not restricted by law from making online reservations for prescription medicines; and
- the user ultimately goes to the pharmacy to collect their order, and can buy additional products.

In other words, C&C models allow for the indirect extension of e-commerce to prescription drugs as well.

From the user's perspective, the greatest advantage of the model is the ability to check the availability of the products they are interested in at the selected pharmacy and the certainty of getting them.

A C&C model has two general versions. In the first version, it is used as a search engine for medicines (drug search engine), i.e. portals bringing together a number of competing pharmacies. Within such a drug search engine, the patient is able to check the availability of a given medicine (e.g. prescription medicine) at the nearest pharmacies. Drug search engines saw increased popularity during the Covid-19 pandemic given the problems with the availability of certain medicinal products. Some of the search engines on the market also offer the possibility of connecting e-pharmacies and starting mail order sales of OTC medicines. Other search engines work closely with healthcare providers by shortening the patient's journey from the doctor's office to the pharmacy.

The second version assumes that the C&C function is restricted to a selected group of pharmacies (e.g. belonging to the same pharmacy chain). The drug reservation function is then added either directly to

online pharmacy websites (the website allows both the purchase of OTC medicines and the reservation of prescription medicines) or by building a separate website dedicated to the reservation of medicines within a given pharmacy chain.



**When developing the C&C model, some basic questions need to be answered from a legal perspective:**

- whether the booking includes the price of the product;
- whether the booking binds the buyer and/or seller;
- how prescription medicines will be presented (remember the absolute ban on advertising these types of products to the public);
- how the pharmacy's patient data will be secured; and
- how to communicate the service so as not to violate the ban on pharmacy advertising.

## Delivery of prescription medicines

Harmonising the rules on mail order of OTC medicines, the Pharmaceuticals Directive<sup>10</sup> left it to the exclusive discretion of Member States to allow or prohibit mail order of prescription medicines. Polish lawmakers have not made a decision about extending mail order sales to prescription medicines<sup>11</sup>. As a result, the sale of such products via the internet remains prohibited in Poland, although there are voices in the public discourse calling for allowing online access to prescription medicines<sup>12</sup>. In fact, online sales of prescription medicines have been allowed in a number of European Union countries, which apply a variety of delivery models safeguarding the interests of both pharmacy operators and patients.

<sup>10</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ EU. L. of 2001, No. 311, p. 67, as amended).

<sup>11</sup> In 2019, a government draft amendment to the Pharmaceutical Law was submitted to the Sejm, assuming that mail order sales of medicines on prescription for persons with disabilities. Ultimately, the proposal was not enacted.

<sup>12</sup> For example, a petition to the Ministry of Health dated 1 December 2023 advocating for supplying prescription medicines by mail order.

Odrębnym zagadnieniem pozostaje jednak kwestia dopuszczalności dostawy leków na receptę przez pełnomocnika. To znaczy sytuacja, w której wyznaczona osoba (przykładowo członek rodziny, sąsiad czy taksówkarz) wykupuje leki (w tym leki na receptę) w imieniu i na rzecz pacjenta. Do sprzedaży leków nie dochodzi na odległość, a bezpośrednio w lokalu apteki, choć bez obecności samego pacjenta. Działanie takie, choć wprost nieuregulowane w przepisach prawa, występuje często w praktyce i nie jest kwestionowane przez organy Inspekcji Farmaceutycznej.

Sytuacja komplikuje się gdy rzeczony pełnomocnik czy concierge wykupujący leki w imieniu pacjenta jest podmiotem gospodarczym zarabiającym zawodowo na dostarczaniu produktów.

Przełgądając bowiem stanowiska strony publicznej z ostatnich kilku lat należy zauważyć dwie sprzeczne tendencje (TAB. 2):

Thus, while the delivery of prescription medicines in exceptional, socially desirable situations is accepted by regulators, the broad business delivery model has been questioned.

In summary, the model of delivery of medicines (including prescription medicines) by proxy has not been regulated in pharmaceutical law. Taking into account the general regulations concerning the way in which proxies function within the framework of economic turnover, such a delivery model should not be deemed as violating the prohibition on mail order sales of prescription medicines, as the sale itself takes place each time at a physical pharmacy. Nevertheless, given the cited negative

**TAB. 2 Regulators' approach to the supply of prescription medicines**

LIBERALISATION	TIGHTENING
Opinion of the Regional Pharmaceutical Inspector (Polish: <i>Wojewódzki Inspektor Farmaceutyczny; WIF</i> ) in Kraków of 3 April 2020 in relation to home delivery of medicinal products to quarantined patients - the Pharmaceutical Inspector has allowed remote filling of prescriptions and delivery of prescription medicines by employees of social welfare centres, uniformed services or volunteers to quarantined patients.	On 18 October 2022, the Małopolski Regional Pharmaceutical Inspector (Polish: <i>Małopolski Wojewódzki Inspektor Farmaceutyczny</i> ), in response to an entrepreneur's request for an individual interpretation (decision ref. No. FAKR-II.850.II.2022), stated that the purchasing of OTC medicines and prescription medicines by third parties (acting on the basis of a proper power of attorney and based on an order) in the name and on behalf of a patient is not allowed.
Communication from the Minister of Health of 15 October 2020 on collecting prescription medicines by persons other than the patient himself - the Ministry confirmed that a pharmacy may sell prescription medicines to a third party.	The decision of the Chief Pharmaceutical Inspector (Polish: <i>Główny Inspektor Farmaceutyczny</i> ) of 25 August 2023, issued as a ruling regarding the model of purchasing medicines on the basis of a power of attorney, held that medicines can only be sold under the rules set out in the Act, and that the model using a power of attorney is contrary to these rules.
The Minister of Health's response to interpellation No. 32091 of 8 July 2019 - the Ministry has permitted the purchasing of medicinal products (including prescription medicines) by employees of social welfare homes, schools and public benefit organisations in the name of and on behalf of a patient - while emphasising that the patient is a party to such an agreement	

opinions of pharmaceutical inspection authorities, the market implementation of such a solution is highly likely to be challenged.

For the sake of safety and legal unambiguity, regulation of the issue of delivery of prescription medicines at a national level should be demanded.

## Other regulatory aspects

### Cross-border sale

Cross-border trade is when an e-consumer purchases products from a seller located in another country. There are many reasons for the increasing popularity of cross-border trade (including in the pharmaceutical sector), ranging from shortages in access to pharmaceuticals to differences in product prices between countries.

In light of the line of jurisprudence set out by the Court of Justice of the European Union (CJEU), based on the provisions of the Pharmaceuticals Directive, national restrictions on mail order sales of OTC medicines were considered to infringe the principle of the free movement of goods guaranteed by the Treaty on the Functioning of the European Union (TFEU). At the same time, the CJEU confirmed the exclusive decision-making power of Member States to allow mail order sales of prescription medicines.

This means that cross-border sales of other categories of pharmaceuticals (including OTC medicines, dietary supplements, medical devices, etc.) benefit, in principle, from the EU's freedom of movement of goods and are allowed as such (provided, of course, that the entity in question has the right to operate a pharmacy under the relevant national legislation). Any restrictions on cross-border sales should be proportionate and justified by the need to protect the health and life of citizens.

However, it is worth noting that the specific legal solutions of the EU Member States (e.g. regarding information obligations towards patients) are not uniform, which leads to practical difficulties in developing cross-border activities.

## Trade in dietary supplements and medical devices

A community (retail) pharmacy (offering both in-store and online services) has the status of a food business operator since it sells dietary supplements (foodstuff). Therefore, when starting to operate a pharmacy, a pharmacy operator must remember specifically about the obligation to register the pharmacy in the register of food business operators kept by the locally competent district (*powiatowy*) sanitary inspector and to transparently inform purchasers about the characteristics of the products.

An online pharmacy also acquires the status of a distributor of medical devices. This status is connected with the obligation to verify the products sold with regard to, among other things, CE markings, manufacturer's data or required information. In addition, the distributor of medical devices is required, *inter alia*, to ensure appropriate conditions for the storage or transport of devices and to provide the manufacturers of the devices with immediate information on received complaints or notifications regarding the medical devices.



### Additional legal obligations

The catalogue of specific legal obligations relating to the marketing of food supplements, medical devices and cosmetic products is extensive. Before starting your business, we recommend a thorough verification of the existing legal obligations.

## E-commerce – regulations

### Consumer rights

An operator who plans to start a business in Poland (including an online pharmacy) must take into account the additional legal protection granted to consumers under, *inter alia*: (i) the Competition and

Consumer Protection Act (Polish: *Ustawa o ochronie konkurencji i konsumentów*) and (ii) the Consumer Rights Act (Polish: *Ustawa o prawach konsumenta*). The authority competent for consumer protection is the President of the Office of Competition and Consumer Protection (Polish: *Urząd Ochrony Konkurencji i Konsumentów*) ("**UOKiK**"). Anyone (in particular, a dissatisfied customer) may notify the President of UOKiK of a suspected breach of collective consumer interests, and, in addition, the authority itself, within the scope of its competence, may undertake an *ex officio* investigation of a case. The President of UOKiK does not deal with individual cases – in this respect, consumers may be assisted by consumer ombudsmen operating at city/district level. Individual consumer cases are decided by civil courts.

### **PROHIBITION OF ABUSIVE CLAUSES**

When operating an online pharmacy, it is important to remember that the contractual terms and conditions (e.g. rules and regulations) used in relation to consumers must not contain abusive clauses. Abusive clauses are provisions which have not been individually agreed with the consumer and which shape the consumer's rights and obligations in a manner contrary to good practice, grossly infringing the consumer's interests).<sup>13</sup> Such provisions are not binding on consumers, although the parties are otherwise bound by the contract. The Polish Civil Code contains an exemplary catalogue of such clauses, including, for example, those concerning the exclusion or limitation of liability or those granting the consumer's counterparty the power to make a binding interpretation of a contract. It is worth noting that, as of 1 January 2021, the provisions on prohibited clauses also apply to sole entrepreneurs<sup>14</sup>.

Such practices consist in particular of breaching the obligation to provide consumers with reliable, truthful and complete information, using unfair

market practices (e.g. by misleading consumers, using aggressive market practices or engaging in acts of unfair competition.

### **PROHIBITION OF PRACTICES INFRINGING THE COLLECTIVE INTERESTS OF CONSUMERS**

Practices restricting the collective interests of consumers (i.e. conduct contrary to the law or morality) are also prohibited. Such practices consist, in particular, of breaching the obligation to provide consumers with reliable, truthful and complete information, using unfair market practices e.g. by misleading the consumer, using aggressive market practice or applying an unlawful code of bad practice or engaging in acts of unfair competition.

### **ADMINISTRATIVE SANCTIONS FOR VIOLATIONS OF THE COMPETITION AND CONSUMER PROTECTION ACT**

If a breach of the prohibition on the use of prohibited provisions is found, the President of UOKiK may issue a decision declaring a provision of a standard form contract to be prohibited, prohibiting its use, and in a decision declaring a practice to be in breach of the collective interests of consumers, ordering it to be discontinued or stating that the practice has been abandoned.

If any of the above-mentioned breaches is found, the President of UOKiK may impose a fine on the entrepreneur in the amount of 10% of the turnover generated in the year preceding the imposition of the fine, as well as order the application of measures to remove the ongoing effects of the breach in order to ensure compliance with the order. However, if, in the course of the proceedings conducted by the President of the UOKiK, the entrepreneur undertakes to take or cease certain actions aimed at ending the breach of a prohibition or removing the effects of the breach, the President of UOKiK may, by

<sup>13</sup> At the same time, they do not apply to provisions determining the main benefits of the parties, including the price or remuneration, if they have been formulated in an unambiguous manner

<sup>14</sup> Where they conclude contracts directly related to their economic activity, but where it is apparent from the content of these contracts that they are not of a professional nature for them.

issuing a decision, compel the entrepreneur to fulfil these undertakings.

If an entrepreneur is fined, an additional fine may also be imposed on a manager of an enterprise who, in the exercise of their function during the period in which the breach occurred, intentionally allowed, by their action or omission, the entrepreneur to infringe the prohibition of prohibited contractual provisions or the prohibition of practices infringing collective consumer interests. The fine imposed on the manager may not exceed PLN 2 million.

## **SELLING OVER THE INTERNET VS CONSUMER RIGHTS**

The Consumer Rights Act contains a number of information obligations to be met by distance sellers, including e-pharmacies. In particular, an e-pharmacy should, in the case of the sale of medicinal products and medical devices, at the latest at the time the consumer expresses their will to be bound by a contract:

- inform the customer on a durable medium in a clear, legible and comprehensible manner of, *inter alia*, the main characteristics of the product, the identification and contact details of the seller, the means of reporting complaints, the total price, inclusive of taxes, the method and time of payment, the seller's identification details, the means of communication, the telephone number for contacting the seller, and the contract term; and
- issue to the customer a contract document or confirm that the contract was executed (within a reasonable time after execution of the contract, at the latest upon the delivery of the goods).

In the event that other products (other than medicinal products or medical devices) are sold online, the online seller must provide to the customer more information on the return of the products.

## **GDPR and data protection**

The operation of e-pharmacies is also subject to data protection regulations. The pharmacy operator will be the controller of personal data not only of

customers/patients, but also of its own employees and associates and the personal data of those working for business partners.

Operating a pharmacy requires compliance with:

- preparation of data protection documentation. Development of appropriate policies, operating procedures, information registers and other detailed documents. These must regulate the way in which personal data protection is organised, the division of responsibilities, the principles of using personal data, the period of storage, the method of data deletion, and issues concerning the security of personal data. A key decision is also the appointment of a Data Protection Officer, responsible for supervising the processing of personal data by the pharmacy.
- provision of information to the data subjects. Provision of information on the principles of the processing of personal data through information clauses or a website privacy policy. These documents describe how data is handled within the e-pharmacy.
- establishment of mechanisms to prevent and handle violations of personal data protection regulations. Procedures for identifying violations, reporting to the President of the Personal Data Protection Office (Polish: *Urząd Ochrony Danych Osobowych*) ("**UODO**"), and notifying data subjects.
- development of mechanisms for collecting consents to personal data processing. Determination of the content, method of recording, use and updating of consents. Consents are one of the legal bases for the processing of personal data, particularly important in the case of data on health status, treatment methods and other special categories of data.
- conduct of a risk analysis for the protection of personal data. Identification of risks and how to mitigate them. Risk analysis requires a combination of legal, security and business expertise to ensure

e-pharmacies are fully compliant with the law. For e-pharmacies, DPIAs (data protection impact assessments) are also required.

- implementation of appropriate safeguards for personal data.  
Technical safeguards (physical, such as locks, and IT, such as anti-virus solutions) and organisational safeguards (policies and procedures). These must ensure confidentiality, integrity and availability of data adequate to the risks and threats identified in the risk analysis.
- training for staff.  
Training on the application of data protection regulations, principles and mechanisms in the daily operation of an e-pharmacy. Should take place regularly (at least once every 12 months) and on an ongoing basis as needed (e.g. after data protection breaches).

### **MAINTAINING GDPR COMPLIANCE**

GDPR compliance is an ongoing process, requiring constant monitoring of changes in the legal, business and technological environment. A person should be appointed to coordinate activities, update documentation, and oversee educational and business activities. The larger the organisation, the more activities it needs to undertake.

### **DATA PROTECTION BREACHES**

Any breach of confidentiality, integrity or availability of personal data must be reported to the President of UODO within 72 hours, even if you do not have all the information (a pre-notification). Every year, the President of UODO receives several thousand notifications of breaches, which can lead to inspections and penalties.

### **THE PRESIDENT OF UODO AND THE CONSEQUENCES OF NON-COMPLIANCE**

Violations of the GDPR can result in penalties of up to EUR 20 million or 4% of a company's annual turnover, whichever is higher. To date, most penalties have been relatively low, with the President of UODO often applying warnings for

incidents with limited privacy implications.

### **DSA REGULATIONS AND THE PROVISION OF SERVICES BY ELECTRONIC MEANS**

The operation of an e-pharmacy also requires compliance with the requirements of the Polish Act on the Provision of Electronic Services (Polish: *Ustawa o świadczeniu usług drogą elektroniczną, UŚUDE*) and Regulation (EU) 2022/2065 of the European Parliament and of the Council on the Digital Services Act (the "**DSA**").

The aforementioned regulations primarily require that:

- Every online pharmacy must prepare and make available regulations for the provision of services by electronic means (Polish: *Regulamin świadczenia usług drogą elektroniczną*). The regulations should be available prior to the execution of the contract and allow for their storage and reproduction. Such regulations should specify, inter alia, the details of the service provider, the services provided, the conditions for the execution and termination of contracts for the provision of services by electronic means and, finally, the complaint procedure.
- Each pharmacy should have a privacy policy readily available on the pharmacy's website. The privacy policy should describe in detail how personal data is processed.
- Like other online operators, each online pharmacy must provide users with access to the following information about the e-pharmacy operator: the name and address of the registered office, the email address and telephone number, and registration data (KRS, NIP). In addition, e-pharmacies should provide a description of the goods and services that they offer, the prices of such goods and services, including taxes and additional charges, information on delivery costs, payment methods, and the procedure for complaints and withdrawal from contracts.

- In the event of the use of cookies that process the personal data of visitors, each user must be informed of the purpose of their use and obtain their consent before processing personal data (before placing cookies on the user's device). This information should be clear and understandable. The pharmacy must record the user's consents to cookies, store information about the consents given, and allow them to be updated. Importantly, the user must be able to consent to different categories of cookies (e.g. technical, analytical and marketing) and to withdraw their consent at any time. There are a number of tools and add-ons available on the market to automate consent collection (both free and paid tools), but before selecting them, it is worth checking that they comply with legal requirements.

A breach of the Polish Act on the Provision of Electronic Services and the DSA may lead to fines imposed by the relevant regulatory authorities. Penalties can be up to 6% of a company's annual worldwide turnover.





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