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Standard of evidence and regulatory coherence in healthcare.

A commentary on the CJEU Judgment of 19 June 2025 in Case C-200/24 *European Commission v. Republic of Poland*

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Abstract: The author analyses in this commentary the CJEU judgment in Case C-200/24 concerning Poland's absolute ban on pharmacy advertising. The conflict between national health regulations and EU internal market freedoms is examined. Using dogmatic and teleological methods, the author evaluates the Court's application of the proportionality and coherence tests. The key finding highlights the "empirical turn" in EU case law, where the Member States must provide concrete scientific data to justify market restrictions. The judgment exposes the inconsistency of the Polish system, which permitted over-the-counter (OTC) sales in non-pharmacy outlets while silencing professionals. This commentary is significant, because it defines a higher standard of evidence in healthcare law and reaffirms the principle of primacy, offering a roadmap for post-2025 legal practice.

Keywords: EU case law, Poland, Court of Justice of the EU, empirical turn, freedom of establishment, regulatory coherence

Standard dowodowy i spójność regulacyjna w zakresie ochrony zdrowia. Glosa do wyroku TSUE z 19 czerwca 2025 r. w sprawie C-200/24 *Komisja Europejska przeciwko Polsce*

Streszczenie: Celem niniejszego opracowania jest analiza wyroku TSUE w sprawie C-200/24 dotyczącej bezwzględnego zakazu reklamy aptek w Polsce. Badany jest konflikt między krajowymi regulacjami a swobodami rynku wewnętrznego i dyrektywą o handlu elektronicznym. Metoda badawcza opiera się na analizie dogmatycznoprawnej oraz teleologicznej wykładni orzecznictwa. Główną tezą jest stwierdzenie wystąpienia tzw. „zwrotu empirycznego”, w którym Trybunał wymaga

od państw twardych dowodów naukowych na uzasadnienie ograniczeń swobód rynkowych. Wykazano również brak spójności polskiego systemu (test hipokryzji) w zakresie obrotu pozaaptecznego. Analiza jest nowatorska, gdyż definiuje nowe standardy dowodowe w sektorze ochrony zdrowia i wskazuje na bezpośrednie skutki wyroku dla polskiej praktyki sądowej, co czyni ją kluczową dla prawników.

Słowa kluczowe: prawo UE, Polska, Trybunał Sprawiedliwości UE, zwrot empiryczny, swoboda przedsiębiorczości, spójność regulacyjna.

The subject of this analysis is the judgment of the Court of Justice of the European Union (hereinafter: the Court or CJEU) of 19 June 2025 in Case C-200/24 *European Commission v Republic of Poland*. This judgment is the culmination of a decade-long dispute over the limits of freedom of communication in the market for pharmacies in Poland. From the perspective of dynamics of the relationship between national and EU law, this judgment can be perceived as a turning point in understanding the principles of the internal market.

The Court of Justice plays a key role in removing obstacles that states place in the way of free trade in Europe – the so-called *negative harmonisation*. This is a process, in which judges do not create new regulations, but eliminate national ones that unlawfully block market freedoms. To this end, judges apply a teleological interpretation, which is focused not only on the words of the provision itself, but primarily on the objective that the EU seeks to achieve: the creation of a single, common area without borders for business.

The main thesis of this analysis is that the Court rightly found the Polish regulations to be excessively harsh and disproportionate. This judgment introduces a crucial principle, which – following contemporary doctrine – is referred to as the *empirical turn*. The empirical turn is a situation, in which a court no longer takes a Member State's justification for the restrictions introduced and demands hard evidence and statistical data to support claims of public interest protection. In paragraph 111 of the judgment, the Court explicitly stated that Poland had failed to provide comparative data on drug consumption before and after the ban, which undermined the credibility of its arguments (see: Judgment of the Court 2025; par. 111).

Since we have established that the Court now requires empirical evidence rather than abstract declarations, we must examine what exactly happened in Poland before this judgment. Without understanding the previous system, it will not be possible to understand why the Luxembourg judges decided to challenge it.

Facts

In 2012, the Polish legislator introduced an extremely restrictive provision into the legal system: Article 94a, Section 1 of the Pharmaceutical Law with absolute ban on advertising pharmacies and pharmacy outlets, with the sole exception being information about the facility's location and opening hours (Judgment of the Court 2025; par. 15).

This strict law led to the development of judicial practice, in which almost any form of communication with patients was considered as illegal advertising. For example, pharmacies were fined for displaying the 'Cheap Pharmacy' sign, providing information about pharmaceutical care programmes, or participating in loyalty programmes. The State Pharmaceutical Inspectorate (GIF) was responsible for penalising businesses. The GIF is a specialised public administration body responsible for overseeing the quality of medicinal products and compliance with drug regulations by pharmacies. These bodies imposed high fines on pharmacists, reaching up to PLN 50 000 for a single violation (Judgment of the Court 2025: par. 1). The Court of Justice imposes the obligation to comply with EU principles of market freedom on so-called corporate authorities. This means that no professional organisation can use its internal codes of ethics to block the freedom to provide services unless these rules are objectively necessary (Kozuch 2015: p. 214).

The introduction of such a broad ban significantly restricted pharmacies' ability to communicate with patients. Since pharmacies were unable to advertise their services, the European Commission (hereinafter: the EC, or the Commission) became involved in the matter, acting as the guardian of the Treaties, ensuring that the Member States do not block fair competition or violate the freedoms guaranteed by EU law. After years of correspondence and Poland's failure to amend the regulations, the Commission filed a complaint with the Court in March 2024 (Judgment of the Court 2025: par. 22). For Polish pharmacies, the advertising ban left businesses facing a double burden. This means that a company must comply with strict rules in its own country, and then again must comply with other, equally strict rules in the country it wishes to expand its services into. According to Zawidzka-Łojek, such barriers are prohibited by the EU's *market access test*. The market access test is a procedure for examining whether a given national regulation (even if it applies to everyone in the same way) does not prevent or unduly hinder new companies from starting a business in a given country (Zawidzka-Łojek 2015a: p. 4).

Legal issue

The European Commission charged Poland with violating key legal acts. These acts are: Directive 2000/31/EC on electronic commerce, as well as Articles 49 and 56 of the Treaty on the Functioning of the European Union (TFEU). Each of these provisions is aimed at protecting businesses from unfair state blockades that could hinder business across Europe.

Firstly, we must analyse the violation of Article 8(1) of Directive 2000/31/EC. This directive constitutes a *superfluum*¹ of treaty norms. As a result, pharmacists now have double protection for their right to inform patients about medicines. Article 8 of this directive stipulates that states must ensure that members of regulated professions (e.g. such as

¹ *Superfluum* refers to a situation, in which a newer provision repeats what was previously enshrined in highly important documents, such as the EU Treaties, so that no one doubts its meaning (Stawiński 2022: p. 475).

pharmacists) can use commercial information within information society services (Judgment of the Court 2025: par. 9, 43). Commercial communication is any form of information intended to promote goods, services, or a company's image (Judgment of the Court 2025: par. 8). In its judgment, the Court rightly noted that the Polish ban was so broad that it deprived the EU regulation of any effectiveness, which in legal terms is referred to as the principle of effectiveness. The principle of effectiveness requires that regulations be interpreted so that they can actually achieve their objectives and not remain a "dead letter on paper" (Judgment of the Court 2025: par. 45).

The classification of a pharmacy's online presence as an 'Information Society Service' is a technical but vital distinction. Under EU law, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient, falls under this umbrella. By applying this to pharmacies, the CJEU effectively 'digitalised' the pharmaceutical profession's right to communicate. This creates a conflict with the traditional 'collegial' view of the profession often held by national bar associations or chambers of pharmacists. These bodies frequently argue that the 'dignity of the profession' is incompatible with commercial competition (Saugmandsgaard Øe 2020). However, the Court's interpretation suggests that the dignity of a profession should not be understood as a static concept, but must evolve. A profession is dignified not when it is silent, but when it provides truthful, helpful, and accessible information to the public. The *superfluum* of treaty norms serves as a safeguard: even if a service is not purely 'electronic', the fundamental freedoms of the TFEU act as a safety net, ensuring that the 'information wall' cannot be rebuilt simply by moving the communication from a website to a physical storefront window.

The Court has long been rigorous in its approach to evidentiary requirements, though not always consistently. When the effectiveness of a measure is in doubt, evidence is required to justify it. However, in this case, the key point was that the E-Commerce Directive (2000/31/EC) and the Services Directive (2006/123/EC) do not permit such an advertising ban, leaving Poland with little chance from the outset. Although advertising of medical services is controversial, clear legislative regulation was crucial. The E-Commerce Directive – and often the Services Directive as well – has a strong impact, where it is applied. At the same time, regulating advertising content, based on interests such as patient safety or preventing excessive use of services, is possible, but requires a cautious and precise approach.

According to the literature on the subject, EU law prohibits the application of national regulations that, in practice, create obstacles to free trade (Zawidzka-Łojek 2022a: p. 352). The advertising ban is precisely such an obstacle, because a pharmacy from another country has no way to inform patients about its offerings, which puts it at a disadvantage from the outset.

Since we have established that Polish law denied pharmacists the right to communicate online, we must now move on to an analysis of the Treaty freedoms. These freedoms are the foundation, on which the entire united Europe was built, guaranteeing the free movement of people, goods, services, and capital.

Internal market freedoms

The Court examined the Polish ban through the lens of freedom of establishment, as defined in Article 49 TFEU (Judgment of the Court 2025: par. 2). This freedom guarantees the right of every EU citizen to establish and conduct business in any Member State under the same conditions as nationals of that Member State. By banning advertising, Poland significantly restricted market access for new pharmacies, especially those from other Member States. A new entrepreneur wishing to open a pharmacy in Poland must somehow inform patients of its existence and the quality of its services. The complete advertising ban made market entry significantly more difficult than for pharmacies operating for years, with an established position and loyal customers (Judgment of the Court 2025: par. 76–77). This solution favoured established entities, which the Court deemed an unacceptable barrier under treaty law.

Equally significant was the violation of Article 56 TFEU, which guarantees the freedom to provide services (Judgment of the Court 2025: par. 3). This freedom allows the provision of services to customers in another Member State without the need to permanently reside in that country. The Polish ban prevented Polish pharmacies from advertising their services to patients from other countries (e.g., in the border area), and prohibited foreign marketing agencies from providing services to Polish pharmacies (Judgment of the Court 2025: par. 68).

Poland attempted to defend this information wall by citing the overriding public interest. In so-called sensitive areas, which include medicines, the Member States have a wide *margin of appreciation*. This is the right of a country to independently decide which values (e.g., health) are most important to society (Zawidzka-Łojek 2019: p. 202). However, this margin is not unlimited, and it is subject of the *proportionality test*. This is a mechanism for ensuring that the government does not use excessively restrictive penalties and prohibitions to achieve goals that could be achieved more leniently. This principle serves to control how the Member States use their powers against ordinary people and businesses (Maśnicki 2022: p. 82). Since the Polish advertising ban was absolute and allowed for no exceptions, it was grossly disproportionate.

The empirical turn

Here, I would like to present a particular perspective on discussed judgment, shaped by the concept of the empirical turn in EU law. The judgment in Case C-200/24 definitively marks the end of an era, in which the Member States could win disputes before the Court by using health protection as a magic slogan, thereby exempting them from the obligation to logically justify their decisions. In this judgment, the Court applied a significantly higher standard of proof to Poland than in previous decades. In paragraph 111 of the judgment, the judges explicitly criticised the Polish government for failing to provide any figures or scientific studies confirming that the advertising ban had actually contributed to a decline in drug consumption (Judgment of the Court 2025: par. 111). This

approach shifts from intuition to evidence. The legislator's intuition, which assumed that a lack of advertising meant fewer purchases, was directly challenged by the lack of data supporting this thesis.

This strict approach to evidence is part of a broader shift in case law that legal scholarship calls the empirical turn. An example of this is the *Scotch Whisky Association* judgment (C-333/14), in which the judges examined whether the introduction of a minimum price for alcohol actually protects human health. The Court found that national legislation can only be deemed appropriate if evidence demonstrates that it genuinely pursues the objective in a coherent manner (Zawidzka-Łojek 2019: p. 204).

The empirical turn also necessitates a discussion on the burden of proof. Traditionally, in matters of public health (TFEU: Art. 36), Member States enjoyed a 'presumption of legality' if they could point to a plausible risk. Case C-200/24 reverses this position. The Court now utilises a standard of a significantly more evidence-based justification than in earlier case law.

If Poland claims that pharmacy advertising leads to medicalisation of society (the excessive consumption of drugs), the Court asks for evidence of demand elasticity. Does a "2-for-1" pharmacy promotion actually cause a patient to ingest more antibiotics, or does it simply influence where they buy the medicine they already need? By demanding statistical data, the CJEU is forcing national legislators to support regulatory choices with empirical evidence. This prevents a situation where laws are passed to satisfy a vocal interest group (such as small pharmacy owners fearing competition) under the guise of protecting the 'uninformed' consumer.

Systemic inconsistency

However, the lack of evidence is only one of the problems with the Polish regulation. The second, equally significant element that undermined Poland's position was the so-called *coherence test*. This is a procedure for verifying whether the state is acting logically and whether it is not prohibiting something in one situation while allowing the same thing in another. Advocate General Mengozzi aptly called this test a *hypocrisy test* in his opinion, cited by Anna Zawidzka-Łojek, (2019: p. 204). In case of Polish pharmacies, this hypocrisy consisted in the state prohibiting the advertising of drugs in secure pharmacies under the supervision of pharmacists, while simultaneously allowing their advertising and sale alongside bread and newspapers in supermarkets.

Whilst analysing the judgment, there was identified a significant inconsistency within the Polish regulatory framework, which the Court exposed in paragraph 109 of the reasoning. Poland argued that it was prohibiting pharmacy advertising to protect people from unnecessary over-purchase of drugs. However, the same medicines (OTC products) that pharmacies cannot advertise are widely available in Poland in supermarkets, petrol stations, and kiosks (Judgment of the Court 2025: par. 109). In general stores, there is no pharmacist available to advise patients, yet the sale and display of medications there are not subject to the same strict prohibitions as in professional pharmacies. The Court cited

a study showing that as many as one-third of respondents purchase over-the-counter medications in supermarkets (Judgment of the Court 2025: par. 109). If the state allows such free circulation of medications outside pharmacies, its argument for the need to silence pharmacies becomes difficult to reconcile with the overall regulatory framework.

This inconsistency is the strongest evidence that the true purpose of the regulation was not health protection, but rather the desire to maintain the *status quo* in the market. The regulatory consistency requirement is currently the most potent tool of the European Commission against the Member States. If the state wishes to restrict market freedoms in the name of higher values, it must do so consistently in every field, not just where it is politically convenient.

Now that we know the system was illogical, we must ask whether there was another way. The Court found that there was, employing the concept of *less restrictive measures*. Less restrictive measures are more lenient methods of regulation that achieve a social goal without completely eliminating economic freedom (Judgment of the Court 2025: par. 113).

Alternative solutions

The judges in Luxembourg emphasised that the Polish government could have controlled the content of advertisements rather than banning them entirely. A ban could have been introduced on aggressive, misleading, or irrational drug hoarding advertisements (Judgment of the Court 2025: par. 113, 121). This approach would have allowed pharmacies to advertise services that genuinely promote health, such as preventive health screenings, which Polish courts previously deemed illegal advertising (Judgment of the Court 2025: par. 104).

It is now time to present the opposing side's arguments. Critics of the liberalisation of advertising regulations also have their arguments, which are worth examining to fully appreciate the significance of the Court's ruling.

Opposing arguments

The most common argument raised by supporters of maintaining the ban was the fear of *commercialisation of health*. Commercialisation of healthcare is a situation, in which an entrepreneur's financial profit becomes more important than patients' safety and well-being. Pharmacy and medical associations warned that allowing advertising would lead to a dramatic increase in drug sales, which could be dangerous to public health.

The second argument was the protection of pharmacist independence. The idea is to prevent a pharmacy owner who is not a pharmacist (e.g., a large chain) from pressuring an employee to sell medications to patients, even if they do not need them (Judgment of the Court 2025: par. 117).

However, the Court rightly rejected aforementioned arguments as inadequate. The advertising ban is not a means to combat the 'greed' of pharmacy owners. As the

CJEU noted, an owner can pressure an employee even in the absence of advertising, and a ban on promoting a pharmacy will not suddenly eliminate dysfunctional personnel management (Judgment of the Court 2025: par. 120). Instead of banning advertising, the state should better monitor ethical standards in pharmacies and ensure the true professional autonomy of pharmacists. Furthermore, advertising can provide patients with valuable information about cheaper alternatives to expensive medications. Such information is beneficial for the patient and does not necessarily mean taking more pills, but simply paying less for them elsewhere (Judgment of the Court 2025: par. 106). In this sense, the CJEU ruling restores patient agency and the right to know.

Impact on the Polish legal system and case law

National judges, when hearing complaints from pharmacies fined for advertising, are required to apply the principle of *primacy*, which states that EU law takes precedence over national law. Therefore, if a Polish provision conflicts with an EU provision, a Polish judge must disregard the national provision and not apply it. This principle is a constitutive element, a common element, without which the entire European Union could not function efficiently (Krajewski 2022: p. 40). This means that a Polish court does not have to wait for the Sejm to amend the law, but can immediately rule in favour of the pharmacy based on the CJEU judgment itself.

The judgment in Case C-200/24 had immediate consequences for the Polish legal system. On 24 June 2025, just five days after the Luxembourg judgment was announced, the Supreme Administrative Court (NSA) issued a landmark judgment in Case II GSK 2635/21. The Supreme Administrative Court, citing the principles of direct effect and primacy of EU law, overturned the decisions of the pharmaceutical inspection authorities imposing fines on a pharmacy for the slogan *Cheaper now!* (pl. *Teraz taniej!*). The Court clearly emphasised that Article 94a of the Pharmaceutical Law in its current form can no longer be applied by Polish administrative bodies (see: Judgment of the Supreme Administrative Court 2025).

This situation also opens the door to claims for damages from the State Treasury for *legislative illegality*.² Businesses can demonstrate lost profits resulting from the long-term paralysis of their marketing activities. The literature emphasises that this principle of liability for damages is intended to ensure the full effectiveness of EU law and protect citizens from the errors of their own governments (Zawidzka-Łojek 2022b: p. 253). Pharmacy owners who have paid unlawfully imposed penalties for years can now seek repayment based on this principle.

In response to these changes, the Ministry of Health prepared a draft amendment to the Pharmaceutical Law, designated UD291. This draft is aimed at repealing the absolute ban and introduce a qualitative regulatory framework that permits advertising as long as it maintains standards of objectivity and neutrality.

² *Legislative illegality* occurs when the state maintains regulations that are contrary to higher-ranking law (in this case, EU law), causing harm to citizens or businesses.

However, this move towards liberalisation has met with significant resistance from professional self-governing bodies, most notably represented by the critical stance of the Lower Silesian Pharmaceutical Chamber (pl. *Dolnośląska Izba Aptekarska*, DIA). In their recent resolution (see: Okręgowa Rada Aptekarska 2026), the DIA expressed a fundamentally sceptical view of the UD291 project, viewing it not as a necessary modernisation but as a threat to the ethical foundations of the profession. The core of their opposition lies in the fear that qualitative standards like 'neutrality' are too subjective to effectively prevent the commercialisation of health. From the perspective of professional self-government, allowing even regulated advertising risks shifting the focus from patient welfare to corporate profit margins, potentially favouring large pharmacy chains with vast marketing budgets over independent, locally-owned pharmacies.

Conclusions

This analysis leads to the unequivocal conclusion that the CJEU's judgment in Case C-200/24 is a legally well-founded and necessary decision. This judgment is a manifestation of the legal order, protecting individual freedoms against arbitrary and illogical state power. The Member State must have solid empirical data before deciding to drastically restrict market freedoms. The healthcare system must be coherent: one cannot prohibit something from professionals while allowing the same in non-pharmacy trade. The right to commercial information is an integral element of the modern services market and cannot be completely abolished under the pretext of professional ethics.

In summary, it should be noted that the Court's rigorous approach to evidence in Case C-200/24 is not a new phenomenon, but rather a continuation and reinforcement of long-standing case law. We refer to this approach by the judges as the *proportionality review standard*. The standard of review is a set of rules, according to which a court assesses whether a Member State's government had sufficient grounds to restrict to restrict the citizens' freedom. The Court requires hard evidence whenever there is reasonable doubt about whether a given ban is actually delivering the promised results. This principle was previously established, among others, in the *Scotch Whisky Association* case, where the judges examined whether a minimum price for alcohol truly protects human health (Judgment of the Court 2015: par. 53–54).

However, it should be emphasised that even if Poland had presented better statistical data, its chances of winning were minimal due to the wording of EU directives – common provisions that all Member States must implement into their laws to ensure that trade rules are similar across Europe. In this case, the E-Commerce Directive (2000/31/EC) and the Services Directive (2006/123/EC) were crucial. These provisions constitute a so-called legislative ban on the introduction of advertising blocks, meaning that the parliaments of EU Member States had already agreed that members of regulated professions must have the right to promote their activities.

Directive 2000/31/EC has a significant impact wherever it is applied. Power refers to EU regulation's ability to invalidate conflicting national laws. Article 8(1) of this directive

protects the right of members of regulated professions (e.g. pharmacists) to use commercial communications online. In Case C-200/24, the Court confirmed that the state cannot use general slogans about the dignity of the profession to introduce a *blanket ban* (Judgment of the Court 2025; par. 45). A blanket ban is one that prohibits everything in a general manner, without taking into account the diverse situations and needs of people.

Although the total ban on pharmacy advertising had to be lifted, the Polish government retained the right to introduce so-called *content regulation*. Content regulation is a principle that does not prohibit pharmacies from talking about themselves, but precisely defines what can be included in such communications to ensure patient safety. It should be noted that protecting people from excessive purchases of medicines and ensuring their safety leaves the state ample room for legislative action. However, such action must be carried out in a targeted and very cautious manner, for example by prohibiting aggressive financial incentives, rather than silencing pharmacists entirely.

These conclusions lead to the view that the judgment in Case C-200/24 ends the era of regulations based on premonitions. From now on, any attempt to restrict the freedom of pharmacies must be supported by facts and consistent with EU law. Thanks to this ruling, Polish patients become informed citizens with the right to reliable information about medical services and drug prices. This is the only way to build a modern and coherent healthcare system that respects both the public good and the principles of the European free market.

This commentary fully endorses the direction taken by the Court. It remains to be hoped that the draft UD291 will not become another tool for the covert reintroduction of restrictions, but will instead serve as the foundation for a new, healthier relationship between the state, pharmacists, and patients.

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