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“PHARMACY FOR THE PHARMACIST” OR FOR THE PATIENT? ON DIFFERENT TRAJECTORIES OF REGULATION ON PHARMACY MARKETS ACROSS THE CEE REGION

Abstract: The landscape of the pharmacy market across the Central Eastern Europe (CEE) region has changed significantly in the past few years. Some countries have decided to liberalize their regulations regarding the shape and size of the pharmacy market (such as Romania and Slovakia), while others have decided to seriously tighten the restrictions and introduce quantitative, ownership, demographic or geographical restrictions according to the “pharmacy for the pharmacist” rule (Poland, Hungary and the Baltic states). The paper presents different models of regulation that shape the pharmacy market across selected countries of the region. Based on desk research and a qualitative survey among representatives of pharmacy chains in the countries in question, the article also explores the issue of the impact of regulations restricting the development of the pharmacy market on the development of new pro-patient pharmacy services. Findings indicate that despite the COVID-19 pandemic having had a significant impact on new pharmacy services development almost everywhere, their inclusion into healthcare systems is easier and wider in countries with less restrictive market regulations.

Keywords: pharmacies, pharmacy market, regulations, market restrictions, deregulation, new pharmacy services, CEE

INTRODUCTION

European legislation is very heterogeneous regarding the establishment, number and functioning of pharmacies. There is no clear pattern of development of the pharmacy market, although some states are following the direction of deregulation and liberalization, while the others rather tend to regulate the existing market more strictly. Scholars point out that a liberalization trend — to the benefit of patients — is rather dominant (Vogler, Arts & Habl, 2006). Such countries as Great Britain, the Netherlands, Norway and Sweden tend to open their markets to improve accessibility of medicines and pharmacy services. On the other hand,

Spain, Austria or France have a high level of state intervention — in the form of market entry barriers — while various ownership and demographic restrictions are maintained.

Currently, pharmacies are changing to respond to the public health challenges and meet patients' needs by shifting the focus from dispensing medicines to patient care and quality of services. This trend, which was strong in Western Europe, extended significantly to CEE region during the COVID-19 pandemic, where patients were offered, among other things, vaccination in pharmacies. During the pandemic, a network of pharmacies near people's homes played an important role as a first line of advice and treatment, supporting local communities and ensuring patients' continued access to basic health care.

In this light, the picture of the CEE countries remains largely unknown. This paper aims to fill this research gap by providing a comparative description of the regulatory situation in selected states across the region: Czech Republic, Estonia, Hungary, Latvia, Poland, Romania, Serbia and, last but not least, Slovakia. To capture this data, the author has analysed the existing secondary data and conducted qualitative research in the form of a survey. The research focused on the three aspects of the functioning of the respective markets, namely legal restrictions on the number of pharmacies, new pharmacy services under consideration for launch in community pharmacies, as well as the regulation of marketing activities. The author summarizes this overview of existing provisions of the legal framework for pharmacies with some general conclusions on their consequences and the possible impact in the future.

METHODOLOGY

This paper is based on desk research and the results of the survey conducted in February 2021 among representatives of pharmacy chains in the eight selected CEE countries: Poland, Czech Republic, Estonia, Hungary, Latvia, Romania, Serbia and Slovakia. Respondents had management functions within the network and were not pharmacists by profession. The survey consisted of a series of 15 open and closed questions regarding the three group of issues. First was restrictions in force on the particular pharmacy market, together with their consequences. The second concerned new pharmacy services, as in many countries pharmacies have played an important role during the COVID-19 pandemic, offering not only provision of essential medicines, but also many additional services. The last set of questions concerned the advertising opportunities. The latter included pharmacies in general, contact details, location and working hours of the pharmacies, information on pharmaceutical care services provided, as well as the possibility of providing information on the OTC products offered. The author treats a survey results as a rather qualitative than quantitative material.

A JOURNEY THROUGH THE REGULATORY FRAMEWORK ON SELECTED PHARMACY MARKETS

CZECH REPUBLIC

Over 2,700 Czech community pharmacies sell and provide advice on medicines, as well as offer some basic diagnostic services (e.g., measuring blood pressure). Pharmacists can own and manage community pharmacies, or work as responsible pharmacists in pharmacies. The ownership of a pharmacy is not restricted to pharmacists: the majority of pharmacies are organized into various pharmacy chains (Nachtigal, Šimůnek & Atkinson, 2017).

Regarding regulatory framework, anyone can open a pharmacy in the Czech Republic and, apart from the need to have an academically qualified professional, there are no other restrictions. In terms of concentration issues, the same rules apply to pharmacies as on any other market. The regulation of the advertising of medicinal products has undergone a long process from the initial total ban on advertising to the establishment of clear rules during the Habsburg Monarchy and the Czechoslovakia period. Some of these, such as restrictions on the advertising of prescription medicines to only the professional healthcare press, are still in force (Vranová, 2012), although the ability to inform patients about the services provided, loyalty programmes and discount campaigns is quite liberal. Many pharmacies have rooms for private consultations with patients, enabling pharmacies to conduct numerous preventive programmes. There is an ongoing debate on possible regulation restricting the emergence of new pharmacies in Czech Republic, however, the serious problem is a decline in the number of pharmacies in smaller towns and villages. Also under discussion are issues related to the possibility of online sales of prescription drugs and a patient home visit services.

ESTONIA

The activities of almost 900 pharmacists in Estonia are similar to those in the other EU Member States. Therefore, professional competencies include dispensing prescription and OTC medicines, compounding extemporaneous medicines or reporting on adverse drug reactions (Volmer et al., 2019). Some new services have recently been launched, such as health screening tests (monitoring blood pressure, blood sugar level, haemoglobin and cholesterol), influenza vaccinations, disease prevention and health education of patients, as well as piloting extended services, such as a review of the use of medications among patients or diabetes screenings. A restriction on new ownership of pharmacies was introduced to the Estonian pharmacy market in April 2020 (Gross, Volmer, 2016). Vertical integration of wholesalers and community pharmacies is not allowed. More than 50% of the shares of a private legal entity (the dominant influence) must be in the hands of a pharmacist working as the manager in at least one of the general pharmacies. Moreover, a pharmacy

licence holder can manage up to four general pharmacies operating in a community with a population of over 4,000. A branch of a general pharmacy may be located in a settlement that is not a city. A branch of a general pharmacy may be located in a settlement of less than 4,000 inhabitants. In a settlement of more than 4,000 inhabitants, a branch of a general pharmacy may also be located in a district of a city, provided that the nearest pharmacy in the city is located in a distance of at least 10 km away. Advertising of pharmacy services or a pharmacy itself, as well as conducting loyalty programmes, is not limited by law. The most challenging issues are lack of financial resources to help pharmacists take over pharmacies during the implementation of the “pharmacy for a pharmacist” rule, lack of support system for the survival of pharmacies in rural areas as well as introduction of new pharmacy services with low governmental involvement versus high public expectations.

HUNGARY

The law on pharmacy ownership in Hungary has been made stricter every year since 2011, resulting in one of the most regulated regimes in Europe. The chains are obliged to appoint a local pharmacist as a director of the pharmacy and were bound to sell at least 25% of their interest to the director or other private pharmacists by January 2014. Furthermore, an obligation was introduced in 2017 that a pharmacist’s share in the pharmacy should exceed 50%. Therefore, almost all pharmacies were pushed under the control of individual pharmacists. There is an additional restriction, limiting the maximum number of pharmacies which may be owned by an individual pharmacist to four. In addition to ownership restrictions, there are also demographic and geographic restrictions. After establishing a new pharmacy, the minimum number of inhabitants per pharmacy must be 4000 in towns with more than 50,000 inhabitants and 4,500 for smaller towns (WHO, 2019). The minimum distance between a new and existing pharmacy must be 250 m or 300 m, depending on the number of inhabitants. Currently, around 8,000 pharmacists work in 2,400 pharmacies. The regulations on marketing activities have been liberalized in recent years. The main challenge in Hungarian pharmacy market, apart from a strict ownership structure, geographical and demographic restrictions, is lack of appropriate guidelines for additional services provided in pharmacies (Felkai, Iván, 2019).

LATVIA

The competencies of around 1,613 community pharmacists in 800 Latvian pharmacies are the supply of prescription and OTC medicines, the management of medicines for some ailments and the provision of consulting and screening services (blood cholesterol, glucose, pressure, etc.). A pharmacist is obliged to provide quality pharmaceutical care to the patients.

A pharmacy in Latvia may be established in the form of a pharmacist's practice, joint practice (a civil partnership) or a company. A pharmacy in the form of a company may operate if no less than 50% of the shares in the company are owned by a pharmacist and/or no less than half of the members of the management board of the company are certified pharmacists. When providing pharmaceutical care in a pharmacy owned by a local government or a person who is not a pharmacist, the respective person must sign a contract with a certified pharmacist. Rules have been introduced on the geographical distribution of pharmacies: 1 pharmacy per 2,000 inhabitants, at least 500 m between pharmacies with extemporaneous dispensing and/or 24-h duty pharmacy service (Muceniece et al., 2018). In 2020, the Latvian Ministry of Health argued that demographic and geographical restrictions should be even greater as there are too many pharmacies. Therefore, the government introduced new rules: quantitative restrictions, 1 pharmacy per 4,000 inhabitants and at least 500 m between pharmacies. Latvian pharmacies are allowed by law to conduct customer and loyalty programmes, as well as to provide relevant information on services. The main challenges on Latvian market are very strict geographic, quantitative and demographic restrictions and a balance between pharmaceutical care and the availability of medicines, pharmacies and financial resources.

POLAND

As in other EU countries, over 11,000 community pharmacies in Poland are the primary entities providing prescription and OTC drugs to patients. More than two decades since joining the EU, the role of the Polish pharmacist is still limited to dispensing medicinal products. The Act on the Profession of Pharmacist, in force since April 2021, established pharmaceutical care and selected pharmacy services. Since then, some new pharmacy services, such as vaccinations or simple diagnostic tests, are being introduced very timidly.

The pharmacy market has been changing for many years as a result of significant changes in market regulations. Today it is subject to demographic, geographical, quantitative, ownership, anti-concentration and information restrictions. It is currently the most over-regulated market in Europe. The regulations in question have been introduced gradually, step by step, over the years. Today, the right to obtain a license to operate a pharmacy depends on having a pharmacist's education and license to practice, the legal form of the business (a pharmacist's sole proprietorship or a partnership of pharmacists), the subject of the business (it cannot be combined, for example, with running pharmaceutical wholesalers), the degree of concentration of pharmacies (you can't get a new license to open a pharmacy if you own or otherwise control more than 1% of pharmacies in the province), the number of entities run or controlled in the country (a maximum of 4 pharmacies is allowed), the demographic criterion (the number of community residents per

1 pharmacy can't exceed 3,000), the geographical criterion (at least 500 m distance between pharmacy entrances).

In 2017, the Polish government introduced new legal restrictions limiting the pharmacy market (Pogorzelszyk, 2020). Since then the new pharmacy licences can only be issued to pharmacies owned by pharmacists. Ownership is limited to a maximum of four pharmacies. What is more, the outgoing Law and Justice government adopted a further tightening of the “pharmacy for pharmacists” rule in 2023. In 2020 the Act on the profession of pharmacist came into force, introducing pharmacy care and new services to the Polish law. Thereafter, thanks to many courses and incentives, initial moderate declared readiness of the staff to promote health (Bojar et al., 2020) has begun to change towards an attitude of openness and willingness of pharmacists to provide new services, such as medication reviews, in community pharmacies (Merks et al., 2022). However, the development of services is effectively blocked by a lack of information about them as in 2012, a restrictive ban on advertising by pharmacies was introduced into Polish law. According to Art. 94a of the Pharmaceutical Law, it is only permissible to provide information on the location and working hours of a pharmacy. Any information on the new services is therefore forbidden, which significantly hinders the spread of this type of service in Poland.

ROMANIA

The activities and occupations of over 13,000 pharmacists in 8,000 pharmacies across Romania are similar to those of community pharmacists in other EU Member States. Their main competences include supplying medicines, giving advice and providing diagnostic services (Sandulovici, 2018).

Community pharmacies in Romania are private institutions. Their owners do not need to be pharmacists as long as they hire a pharmacist as the manager. The rule of demographic proportionality is established by law: Bucharest has one pharmacy per 3,000 inhabitants, towns that are the capitals of their respective counties have one pharmacy per 3,500 inhabitants, while other towns have one pharmacy per 4,000 inhabitants. The exceptions are the community pharmacies found in railway stations, airports and in large shopping centres. No demographic criterion is applied in rural areas. The law initially provided for a geographic criterion regulating the minimum distance between two pharmacies (at least 500 m, subsequently reduced to 250 m), but this was ultimately eliminated. Advertising of a pharmacy and services is allowed by law, although pharmacies cannot advertise medicines (Rx nor OTC). They are allowed to present commercial catalogues and price lists to the general public, provided that they do not contain any elements of a promotional nature and that they are only presented inside the premises of the pharmacies. In Romania, a brain drain of pharmaceutical graduates to other EU countries as a consequence of the harmonization of EU norms poses a serious

challenge. In addition, as in many other countries, very challenging are the disparities in the location and geographical access to pharmacies in rural areas. Also, there is a lack of clear legal status of e-pharmacies.

SERBIA

As in other former Yugoslav republics, a substantial number of community pharmacies in Serbia (about 1,000 of over 3,700) are still owned and operated by the state (“public pharmacies”). In addition, some pharmacies are run by private entities. Opening new pharmacies is not limited by law, which is resulting in a large number of pharmacies, especially in cities. A debate is ongoing about the scope of the new pharmacy services in Serbia, including such additional services as counselling, demonstration and verification of the use of inhalation devices and insulin pens.

Since 2017, there has been a public debate in Serbia on the introduction of demographic and geographical criteria for newly opened pharmacies. Such restrictions, together with the geographical criterion of a 200 m distance between pharmacies and a demographical criterion of 4,000 inhabitants per pharmacy, currently apply only to the state-owned pharmacies. The Optimization Plan for the Network of Health Care Institutions is currently being discussed as a part of the process of decentralizing healthcare in Serbia. Pharmacy facilities are also a part of the plan. The above rules on demographics and geography are also intended to encompass private pharmacies which are about to open. One of the main challenges of the pharmacy market in Serbia is decentralization and privatization of public pharmacies (now governed by local authorities).

SLOVAKIA

In Slovakia, over 2,000 pharmacies are currently in operation. Market structure and competition rules are relatively liberal. Ownership and geographical distribution of community pharmacies are not restricted by any rules. The number of community pharmacies per 100,000 inhabitants is currently among the highest in the OECD countries (OECD, 2019). Despite multiple changes in ownership regulations and geographic and demographic restrictions in the past, density and quality coverage of the availability of pharmaceutical services in Slovakia is now perceived as relatively sufficient. Slovakia is also a leader in the implementation of e-prescriptions.

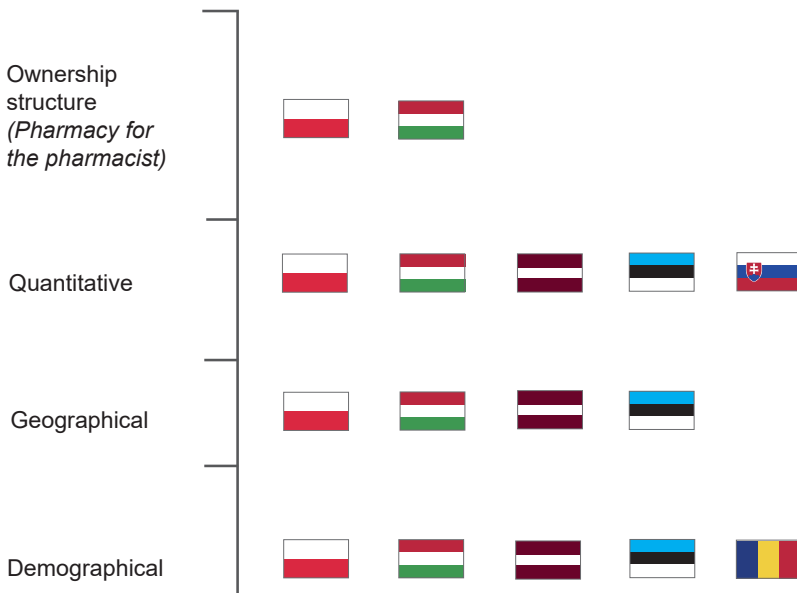
Until 2004, certain geographic and demographic restrictions applied to the opening of a new pharmacy, such as an obligatory distance of 500 m from another pharmacy and a rule of 5,000 inhabitants per pharmacy. The liberalization of pharmacy ownership was approved in 2004. Anyone, not only a pharmacist, became eligible to obtain a permit for the provision of pharmaceutical care. Another

significant change took place in 2011 with the adoption of a law abolishing the restriction that one owner could own only one pharmacy. This allowed for horizontal integration and allowed pharmacy networks to arise legally. The law limited ownership to only one pharmacy per one natural or legal person again in 2013. Therefore, every pharmacy is officially a separate company. As for regulations on marketing activities, a pharmacy is entitled to conduct loyalty programmes as well as provide discounts and benefits to patients, but only for OTC medicines. Among the biggest challenges of the pharmacy market in Slovakia are the decline in the number of pharmacies in smaller towns and villages. The development of a modern patient-centred approach is also needed in Slovak pharmacies, together with the reimbursement of new pharmacy services from public health insurance funds.

DATA ANALYSIS & RESULTS

RESTRICTIONS IN THE NUMBER OF PHARMACIES

Respondents of the survey have indicated the following restrictions in force in individual countries (by market size):



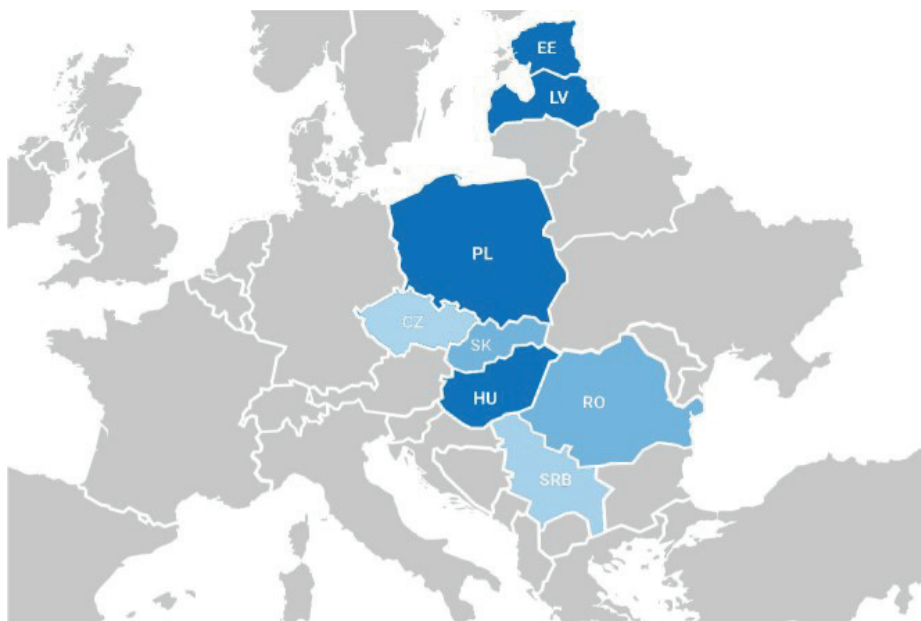
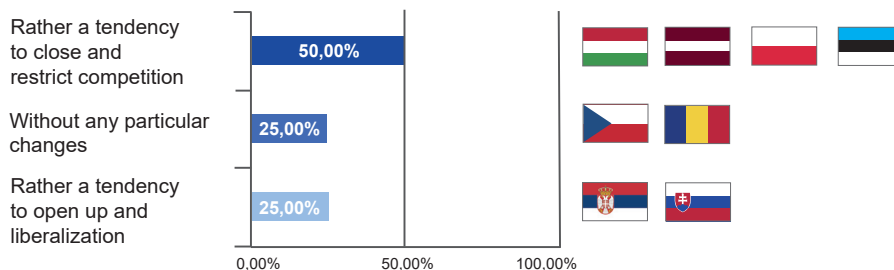


Figure 1: Regulatory restrictions limiting the number of pharmacies:



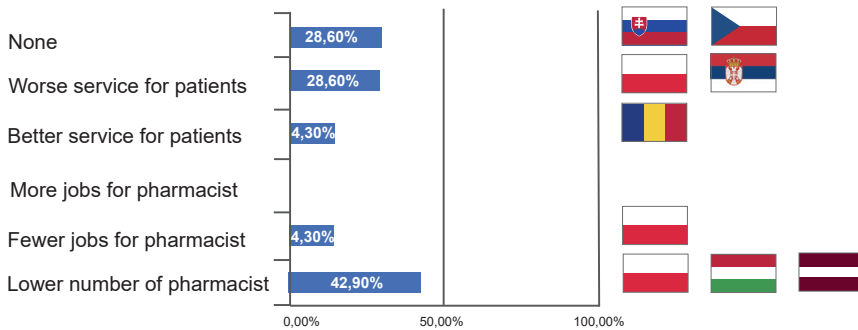
As much as the four respondents from analysed countries indicated that all types of restrictions (ownership, quantitative, geographical and demographical) are in force on their markets of operation.

Then respondents were asked: “How would you rate the degree of regulation of the pharmacy market in your country?”.



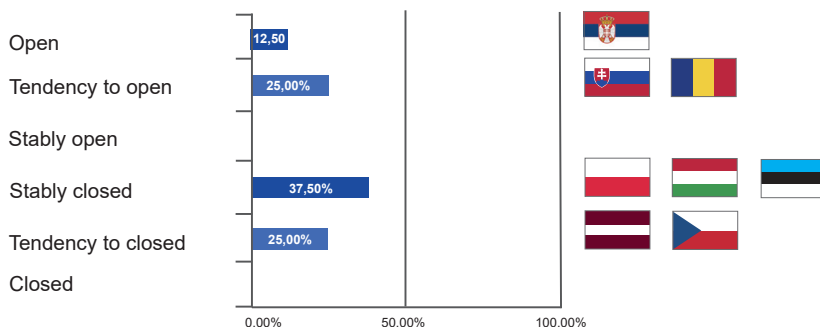
Here as expected Estonian, Polish, Latvian and Hungarian pointed to impression of a strongly closed pharmacy market, while Slovenian and Serbian indicated rather a tendency to liberalisation of the market.

Later respondents answered the question: “What are the main consequences of these restrictions on the pharmacy market in your country?”. Polish respondent pointed to the consequences related to worsened services offered to patients as well as shrinking workplaces for pharmacists.



Respondents then answered the question: “How do you perceive the consequences of these restrictions?”. Estonian respondent indicated that: “Restrictions on ownership have resulted in a major increase of bureaucracy and paperwork. Little to no pharmacists, who wish to take on the role of the owner of the pharmacy(ies)”. The Polish representative pointed out other consequences of the restrictions on the pharmacy market: “Inability to expand pharmacy chains, a risk of liquidation of pharmacies, restriction of the range of services that can be provided to patients”. Slovakian respondent referred to results of limited ownership to only one pharmacy per one natural or legal person, pointing out that the biggest challenge is “Administrative complexity for managing a large pharmacy chain. You formally manage hundreds of companies”. Respondent from Hungary raised the issue of the “pharmacy for pharmacist” rule: “Restrictions in ownership, management rights regarding pharmacy issues, excluded all managers who are not pharmacists”. Respondent from Latvia underlined that market limitations are strongly connected with the business situation: “Politically — the ability to open new pharmacies is limited. Economically — there is a lot of price competition from pharmacies, so the profit is declining”.

Then the respondents were asked: “What do you think the pharmacy market (in your country) will look like in the next 10 years?”.



Regarding the future, interesting case is presented by Romania as the representative expects the regulatory open market to be maintained. As the answer to one of the previous questions shows, in his opinion, this openness of the market favours the quality of services for patients. Despite the trend towards closed markets in recent years, none of the survey respondents expects a closed pharmaceutical market model to be introduced in the coming years.

NEW PHARMACY SERVICES

There are many pharmacy services offered to patients in pharmacies worldwide apart from dispensing drugs and medicines, such as vaccination, realisation of preventive programs, drug reviews, realisation of preventive programs, consulting in prevention of addictions, nutritional consulting, preparation of personalized drugs dosing system and others. In the survey the author have asked, what kind of new pharmacy services are under discussion in particular countries. Respondents indicated such services as vaccinations, drug reviews, evaluation of hearing, blood pressure and glucose measurement, support in quitting smoking, spirometry, cholesterol measurement, early detection of skin condition, early detection of Alzheimer’s disease, development of individual pharmaceutical plans and early detection of osteoporosis.

Therefore, the respondents were asked: “If they are approved by the government, would you like to provide them to patients in your pharmacy/chain?”



Figure 2: Willingness to introduce new pharmacy services for patients:

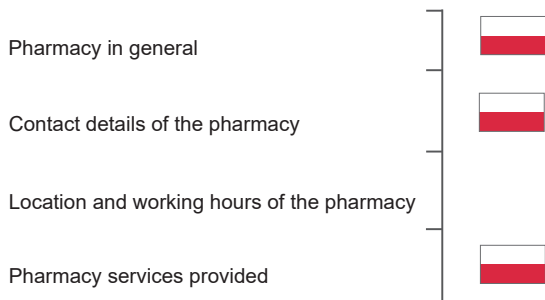
All types
 Selected types

Respondents working for pharmacy chains in Poland, Romania, Serbia, Estonia and Slovakia have declared themselves fully open to implementing all types of services accepted by the government.

ADVERTISING BAN

As indicated earlier, a restrictive advertising ban is in force only in Poland. As stated in the Pharmaceutical Law, only information about the location and working hours of a pharmacy or a pharmacy outlet is not advertising. This was confirmed by the respondents of the survey that were asked:

“Is it forbidden to inform patients on...?”.



In Poland, it is not only the advertising of pharmacies that appears to be problematic, but also the possibility of informing patients about pharmaceutical care provided by pharmacists, even though such rights derive directly from the law. Other analysed countries face only advertising ban on reimbursed products.



Figure 3: Ban on marketing activities:



The restrictive interpretation by the Pharmaceutical Inspectorate of the ban on pharmacy advertising means that pharmacy entrepreneurs in Poland have to operate under considerable legal uncertainty. Even when they consider taking legal informational action, they fear that it will be challenged. Currently, there

is a public debate in Poland on the exemption from the advertising ban for information about new services provided in a pharmacy (Ojczyk, Redmerska, 2021). Also under consideration is the introduction of an obligation for every pharmacy to inform patients about the scope of the health services it provides, as is the case for healthcare providers, which make public information about the scope and types of services they provide. This issue will undoubtedly be the subject of further public debate in Poland as Polish patients will expect an increasing range of additional services in pharmacies. This is evidenced, for example, by the high declared satisfaction of patients regarding pharmacist-administrated vaccination (Grzegorzyc-Karolak et. al, 2022).

CONCLUSIONS

THE TWO OPPOSITE DIRECTIONS

As can be seen, the degree of regulation of the pharmacy market regarding restrictions in the number of pharmacies varies substantially across the CEE region. Such countries as the Czech Republic, Slovakia, Romania or Serbia are tending to liberalize and open their markets. This trend seems stable and market representatives do not expect a significant change in this direction in the coming years, except for the Czech Republic, where a new trend towards the closing of the market is visible. The Slovakian model, with a single pharmacy principle, poses some administrative troubles, but is not an effective barrier for the development of pharmacy chains.

On the other hand, Poland, Hungary and Baltic countries represent the opposite trend. In Hungary and Latvia this direction has progressed for around a decade, while the Latvian government recently introduced even stricter demographic restrictions. Over the past few years, Poland and Estonia have been introducing many new restrictions on the market. Pharmacy ownership in Estonia was restricted to pharmacists last year. All four main market limitations (ownership, quantitative, demographic and geographic criteria) have been applied simultaneously in Poland since 2017. The situation is the same in Hungary and Latvia. This poses numerous questions about the legitimacy and possible effects of such over-regulation.

THE MORE RESTRICTIONS, THE WORSE FOR PATIENTS

When analysing the emergence of new pharmacy services, it is clear that markets with opening tendencies with regard to the simultaneous number of pharmacies are far more open to discussion and the introduction of innovative services for patients. While market representatives are willing to introduce services to a similar extent, not everyone will have such an opportunity because of the attitude

of the government to new services, as it currently is in Estonia. Some respondents directly stated that the restrictions of the market size translate into a worse (Poland) or better (Romania) service for patients.

An interesting phenomenon — with respect to not only the CEE, but the EU in general — arises in Poland with its total ban on advertising activities, which has been in force for nearly a decade. None of the other countries have such strict restrictions. This poses numerous challenges in the face of the expanding role of community pharmacists, especially during the COVID-19 pandemic. Although COVID-19 has challenged the health care system, it has also provided an opportunity for development of novel and innovative services in pharmacies, such as vaccination (not only against coronavirus), telepharmacy, drug reviews, and other (Tanapong, 2022). Existing legal barriers need to be removed or liberalized in order to secure new pharmacy services and ensure appropriate information addressed to patients. The Polish example presents an important lesson to other markets about the need to consider the long-term effects when introducing further legal restrictions under the guise of benefits for the market and the patients themselves.

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