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The legal extension of the role of pharmacists in light of the COVID-19 global pandemic

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\textbf{ABSTRACT}

\textbf{Background:} The COVID-19 epidemic has affected every area of life. The greatest challenge has been to adapt the functioning of the health service to prevent the spread of the epidemic and to help infected patients. This has required the involvement of not only doctors and nurses, but also pharmacists. In the face of this pandemic, governments in many countries have granted pharmacists greater authority.

\textbf{Objectives:} The purpose of this paper is to review the legal extension of the role of pharmacists in light of the COVID-19 pandemic. The review considers recent changes in European countries, Canada, and the United States.

\textbf{Methods:} A literature review was performed to summarise knowledge about the extension of the role of pharmacists during the pandemic period. Key articles were retrieved mainly from PubMed and Google Scholar, using the terms “COVID-19”, “2019-nCoV”, “coronavirus”, and “pandemic” in combination with “pharmacist” as keywords for our search. We included scientific publications from February 1, 2019 to May 15, 2020.

\textbf{Results:} Pharmacists have been given numerous opportunities so that they can actively join in the fight against the virus. Some of the novel legal extensions aimed at aiding overloaded healthcare systems are as follows: authorisation to prepare hand and surface disinfectants, eligibility to renew chronic treatment prescriptions, as well as filling pro auctore and pro familia prescriptions by pharmacists, performing COVID-19, influenza, and Group A Streptococcus screening tests, and vaccine administration. Moreover, many countries have facilitated Internet services, such as virtual medical consultations, e-prescriptions, and home drug delivery – to promote social distancing among patients. To mitigate drug shortages, the following strategies have been implemented: alternative sourcing, generic, or therapeutic substitution, and preparing compounded formulations at the pharmacy.

\textbf{Conclusions:} Novel legal extensions have allowed exploitation of the full potential of pharmacists worldwide, aiding the limited resources of overloaded healthcare systems.

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Introduction

Pharmaceutical care is focused on the patient pharmacy practice, with the following aims: to protect public health through healthy lifestyle promotion, prevention of diseases, as well as assessment, initiation, and supervision of the proper course of pharmacotherapy in close cooperation with the patient and, if necessary, with other healthcare professionals. In addition, pharmaceutical care aims to ensure the safe and rational use of drugs to optimise the patient’s health-related quality of life, achieve positive clinical outcomes, and reduce treatment costs.1

Over the past four decades, the role of the pharmacist has evolved from that of medicine supplier towards that of a provider of services and information, and finally - to provider of patient care by actively participating in the treatment process. Increasingly, the pharmacist’s task is to ensure that a patient’s drug therapy is appropriately indicated, the most effective available, the safest possible, and convenient for the patient. By taking direct responsibility for an individual patient’s medicine-related needs, pharmacists can make a unique contribution to the outcome of drug therapy. The important role of pharmacies, which form an integral part of the healthcare system, should be emphasised in the daily delivery of medicines, therapeutics, vaccines, and key health services to the public. It is well known that pharmacists are among the most accessible healthcare professionals; in many cases pharmacy staff are available 24 hours a day. The role of pharmacies in a crisis, such as the current pandemic, is of crucial importance because they are often the first and the last point of contact with the health care system for patients who need reliable information and advice. Pharmacists have already confirmed their important role in emergencies, including during the previous pandemics of H1N1 influenza and SARS.2–4 Pharmacists play an important role in patient care during a pandemic both in community pharmacies5,6 and in the hospital setting.7 Although the main focus of healthcare services is to respond to COVID-19, people still have other non-COVID-19-related symptoms and conditions that require professional attention.8 During a time of pandemic pharmacists should concentrate not only on reducing the possibility of virus spread but also on patients’ daily needs related to taking medicines. Also, patients requiring special attention, such as after haematopoietic cell transplantation or during cell therapy, can benefit from the involvement of pharmacists in their therapeutic process during the COVID-19 pandemic.9

The special needs of community pharmacy services during the COVID-19 pandemic should include the following:

- promoting pandemic control;
- actively providing guidance to the community patient population regarding chronic disease management, to improve patients’ medication adherence and support their self-monitoring of the effectiveness and safety of current therapy;
- instructing patients to take home medications on time and in the correct dosage, emphasising the importance of adherence in chronic disease control and in avoiding unnecessary hospital visits during the pandemic;
- making sure the medication is within the period of validity before taking;
- informing patients on the availability of drug delivery or mail order services provided in the pharmacy and encouraging patients to use such services during the pandemic if needed;
- educating chronic-disease patients to perform self-monitoring on disease symptoms and adverse drug reactions at home;
- providing additional guidance for patients with cancer, inflammatory bowel disease, or other special chronic diseases or patients taking high-risk medications chronically, based on the characteristics of the diseases or medications;
- providing psychological support. Pharmacists should pay attention to patients’ emotional and psychological conditions and identify patients with excessive anxiety, concern, or fear;
- providing factual and reliable information on the diseases and associated symptoms, e.g. COVID-19.

The COVID-19 pandemic is an ideal time to update the regulations in order to extend the role of pharmacists in pharmaceutical care. The goal of this paper is to perform an overview of the legal possibilities of pharmacists during the pandemic period.

Methods

Using online databases, a systematic literature review of the legal regulations related to pharmacy for COVID-19 was carried out. Key articles were retrieved mainly from PubMed and Google Scholar using the terms ‘COVID-19’, ‘2019-nCoV’, ‘coronavirus’, and ‘SARS-CoV-2’ as keywords for our search. We included scientific publications from February 1, 2019 to May 15, 2020. Only publications focusing on the role of the pharmacist in the SARS-CoV-2 pandemic were eligible for inclusion. We screened all reference lists of relevant studies in order to identify any missing publications.

Pharmacy community activities related to COVID-19: A review

Most EU countries have focused on communications to pharmacists about how to protect pharmacy staff and patients from the spread of coronavirus. Community pharmacies have expanded their role in providing patients with best care possible during the COVID-19 pandemic. Examples of some of the ongoing and planned services and activities in different countries throughout the world are included in Table 1. Most of them required some legislation support to be legally permitted. The rest show how pharmacists have broadened their actions to use available resources and their knowledge to the maximum extent in the current arduous circumstances. Actions undertaken by pharmacists may play a vital role in enhancing the efficiency of overworked health systems.

One of the challenging problems arising during pandemics like the current COVID-19 pandemic is a shortage of medicines. Examples of the legal solutions for mitigating them in European countries are listed in Table 2.

Basic knowledge on COVID-19, particularly the onset symptoms and transmission routes, may be provided by pharmacists to help the community population understand the pandemic situation properly and to promote early identification of suspected individuals.10

Discussion

As stated in this article, an extensive range of new responsibilities have been introduced into the community pharmacy setting to expand the role of the pharmacist in the face of the pandemic. First and foremost, pharmacists are responsible for implementing guidelines aimed at ensuring patient and staff safety. One of the most difficult parts of this task is to promote social distancing. Pharmacists should organise pharmacies in such a way as to make it difficult for the virus to spread. These actions are particularly important due to an increased number of patients, especially at the beginning of the pandemic and just after the first news on this issue had been published by the media. Temporary barriers are designed to limit the number of patients in the pharmacy at any given time and to increase the distance between patients. However, the introduction of safeguards and procedures has led to a significant financial burden. Another threat to the financial stability of a pharmacy may be its temporary closure due to lack of staff – for example, because of unexpected quarantine.15

The most important pharmacists’ tool, however, is persistent patient education on how to behave in the pharmacy and, in a broader context, how patients can protect themselves from infection. Two areas of this education should be highlighted in particular. Firstly, this education will be frequently initiated as a response to patients’ questions, but it
Table 1 Pharmacy community activities related to COVID-19 in different countries.

| Country          | Actions                                                                                                                                 |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Austria          | · Implementation of e-prescriptions in Austrian pharmacies. · Major relief concerning the prescribing of narcotics and substitution patients. In March the Federal Ministry of Health created some relief in this area for the duration of the coronavirus crisis. For example, regarding dispensing rules for opioid substitution treatment - pharmacists can dispense larger quantities so the patient does not have to come to the pharmacy every day. |
| Belgium          | · Permission to denature alcohol by Belgian pharmacists. · Granting exclusive authorisation for pharmacies to sell certain medical devices, individual protective equipment, and biocides, including hydroalcoholic gels and masks, with the following restrictions: · the government reserves the right to request the stocks of all the above-mentioned products at any time to organise possible better distribution between pharmacies. · the delivery of those products to private individuals in the retail trade is subjected to the prescription of a professional care provider, which includes pharmacists. · pharmacists can decide in good conscience who is the priority target group for the distribution of these devices (e.g. family members of an infected person, a patient with immunosuppression or under immunosuppressive treatment, etc.). |
| Czech Republic   | · Permission to compound antiseptic solutions. · Implementation of e-prescription of orthopaedic aids. |
| Finland          | · Permission to compound hand disinfectants by pharmacies. |
| France           | · Authorisation of pharmacies to prepare hydroalcoholic gels, following World Health Organisation (WHO) recommendations, if they are out of stock. · Exceptional renewal of chronic treatment by community pharmacies. · Launching a special code in pharmacies for victims of domestic violence. |
| Germany          | · Temporary authorisation for pharmacies to prepare hydroalcoholic gels for pharmacy use, following WHO recommendations, if they are out of stock. |
| Italy            | · Decrease for pharmacists to give oxygen to patients, also at home. · Introduction of e-prescriptions. · Medicine home delivery service to vulnerable people by Red Cross and Federfarma. · Promoting the preparation of disinfectant products by pharmacies, also to counter speculative prices. |
| Netherlands      | · Implementing remote consultations with patients (video calling, telephone, e-mail) to ensure continuity of pharmaceutical care, using guidelines provided by The Royal Dutch Pharmacists Association. · Taking part in a domestic violence campaign launched specifically during the coronavirus period. Using code word ‘mask 19’, patients at the pharmacy can say that they are victims of domestic violence. · Developing four preparation instructions for a liquid hand alcohol and a viscous gel: two based on ketone alcohol and two based on isopropyl alcohol, all intended for professional use. |
| Poland           | · Shorter period for transferring funds to pharmacies from the National Health Fund (at the latest the day after positive verification of the documents sent to the pharmacy). · Permission for pharmacists to prepare ethanol antiseptic solutions for the skin. · Patients can get reimbursable medical devices via courier. It is acceptable to receive it without signing appropriate forms by the patient (as is needed when getting reimbursable medical devices directly from the pharmacy). · The possibility of issuing pharmaceutical prescriptions by pharmacists for themselves and some family members (“pro familia prescription”) - also reimbursed - and the possibility of writing a pharmaceutical prescription for patients in the event of health endangerment, with 100% payment, with different limitations (for example, not only the smallest pack available at the pharmacy, but up to 180 days of therapy). · A maximum of three people can be in a pharmacy per cash desk (providing a distance of minimum 2 m). · Only patients aged over 65 years can stay in the pharmacy between 10:00 and 12:00 (except in emergency situations). · All patients in the pharmacy are obliged to wear disposable gloves. |
| Portugal         | · Extension of the emergency medicine delivery line to the whole country (this free line was only available, due to pilot testing, in the Bragança region and in Loures and Odivelas municipalities). The line, called SAFE, allows patients to know in which pharmacy the medicines they need are available. The pharmacy, after accepting and confirming the availability, is responsible for contacting the patient and defining the delivery and payment methods. With this system, there is a possibility to establish a connection, at a distance, between patients and pharmacies, maintaining the medicine dispensing service. · Establishment of a new protocol for home delivery of medicines – a partnership Associação Nacional das Farmácias (ANF) with the Portuguese post office service, in which it helps pharmacies nationwide to deliver medicines to people’s homes. |
| Spain            | · The General Council of Pharmacists and the Red Cross have signed an agreement, with the authorisation of the Ministry of Health, so that all people particularly affected by the pandemic can have access to their medication without leaving their homes. The network of 22,102 pharmacies and more than 200,000 Red Cross volunteers have joined forces to facilitate the delivery of medicines at home to quarantined patients, those with mobility problems, chronic respiratory diseases, diabetes, and cardiovascular diseases. · Authorisation of community pharmacies to dispense hospital-only medicines to patients who need to take their medication in hospitals. |
| United Kingdom   | · The extension of the Minor Ailment Service and increased access to Emergency Care Summary Data. · The right to supply certain controlled drugs to patients without a prescription. · Pharmacord eTool (an online consultation guidance and record-keeping platform) to carry out virtual consultations with patients remotely using WhatsApp, FaceTime, or Skype. When treatment is recommended, patients can either pick it up from the pharmacy or decide to have it posted to their home. · The possibility of home delivery of medicines to self-isolating patients during the COVID-19 outbreak. |
| United States    | · Invocation of emergency pharmacist authorities to allow for pharmacist refilling. · Creation by community pharmacies of COVID-19 testing sites. |
should not be limited to a simple explanation and should include other key areas of infection prevention. Secondly, it is important to inform patients that the recommendation is based on current knowledge, so it is necessary to regularly update the obtained information. Forming this habit can also help to improve adherence and, consequently, patient safety.

The importance of the role of the community pharmacy in the protection of public health can be seen in the example of the COVID-19 pandemic. More integrated incorporation of community pharmacies in the pandemic management should also be an integral part of national policy. Even in countries where pharmaceutical care is not significantly developed, previous experience has shown that a community pharmacy is a great place for promoting public health, particularly due to increased education initiatives.44

However, the fundamental role of the pharmacist is still to dispense medications. This vital service is inevitably related to the profession and the place of the community pharmacy in the healthcare system. Thus, the pharmacist must ensure that patients have uninterrupted access to medications. The coronavirus SARS-CoV-2 pandemic, on the one hand, led to a deterioration of the geopolitical situation, affecting the availability of medicines. It is worth mentioning here the importance of the role of China, the first country to be hit by the coronavirus, which, as a major producer of active pharmaceutical ingredients (APIs), remains an important player in drug distribution.45,46

Secondly, the supply of medicines is hampered by the significantly increased demand for medicines and food supplements at the beginning of the pandemic.46

Another area worth summarising is the recently modified range of pharmaceutical services. In the face of the pandemic, governments have introduced new pharmaceutical services and have expanded those existing in legal systems so far, particularly in the area of prescribing. This process is supported by e-health. In this context, it is worth recalling the example of Poland, in which pharmacists’ prescriptive authority has been expanded recently. Pharmacists were granted the right to prescribe drugs for themselves and their closest relatives, and those prescriptions are reimbursed from public sources, in the same way as when a similar prescription would be issued by a physician. In different cases, pharmacists can issue a pharmaceutical prescription for patients in the event of a health emergency, not just in life-threatening cases, as it was before, but without reimbursement (full patient payment). Moreover, in terms of prescriptive authority, Canadian pharmacists are allowed to prescribe some controlled medications under special circumstances.

The different set of new responsibilities is associated with compounding antiseptics. Due to the temporal shortage of antiseptics, this role is an important step to minimise the pandemic. This service, as summarised in this paper, has been introduced in most European countries. Some services are strictly unique, e.g. French pharmacists can report the complaints of female victims of domestic violence. From a historical perspective, this service represents a new area of psychological intervention that can be introduced into the community pharmacy and reinforce new thinking about the potential future role of pharmacists. Home-based services are also implemented only if social distancing can be maintained to protect patients and pharmacists from unwanted contamination.

Table 1 (continued)

| Country     | Actions                                                                 | Country     | Actions                                                                 |
|-------------|--------------------------------------------------------------------------|-------------|--------------------------------------------------------------------------|
|             | · Creation of a student-pharmacy connection portal to ensure that front-line pharmacy professionals can contact students able to volunteer under their supervision, thereby increasing support of pharmacists on the front lines of care.44 |             | · Introduction of permission for vaccine administration by a pharmacist after completing training.45 |
|             | · Permission for pharmacists to test and initiate treatment for influenza and Group A Streptococcus.46 |             | · Extension of the rights of pharmacy technicians for permission to administer vaccines, perform remote data entry, and take new orders.46 |
|             | · Increase in telepharmacy services in hospitals.46                        |             |                                                                         |
|             | · Development of a national public health telepharmacy service.46          |             |                                                                         |
|             | · Development of a national public health telepharmacy service.46          |             |                                                                         |
|             | · Creation of a national public health telepharmacy service.46             |             |                                                                         |

Table 2

Legal solutions for medicine shortages in European countries during the COVID-19 pandemic period.47

| Country     | Mitigating solution                                                                 |
|-------------|-------------------------------------------------------------------------------------|
|             | Sourcing the same medicine from alternative authorised sources (nationally)          |
|             | Changing to the same medicine with a different strength                              |
|             | Generic substitution                                                                |
|             | Therapeutic substitution                                                             |
|             | Preparing a compounded formulation                                                  |
|             | Importing the medicine from another country                                         |
| Austria     | ✓                                                                                   |
| Belgium     | ✓                                                                                   |
| Croatia     | ✓                                                                                   |
| Cyprus      | ✓                                                                                   |
| Czech Republic | ✓                                                                                   |
| Denmark     | ✓                                                                                   |
| France      | ✓                                                                                   |
| Germany     | ✓                                                                                   |
| Greece      | ✓                                                                                   |
| Ireland     | ✓                                                                                   |
| Italy       | ✓                                                                                   |
| Latvia      | ✓                                                                                   |
| Malta       | ✓                                                                                   |
| Norway      | ✓                                                                                   |
| Netherlands | ✓                                                                                   |
| Poland      | ✓                                                                                   |
| Portugal    | ✓                                                                                   |
| Romania     | ✓                                                                                   |
| Slovak Republic | ✓                                                                                   |
| Slovenia    | ✓                                                                                   |
| Spain       | ✓                                                                                   |
| Sweden      | ✓                                                                                   |
| United Kingdom | ✓                                                                                   |
Conclusions

In summary, all these actions are aimed at minimising the number of medical consultations, consequently leading to rationalisation of limited sources. The further expansion of services depends on the severity and the duration of the pandemic.

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P.M, E.D, M.J, and D.S are registered pharmacists with the Polish Pharmaceutical Chamber and are bound by the codes of practice and ethics. At the time of preparation of this manuscript P.M is employed as an advisor to the Management Board of the Polish Pharmaceutical Group S.A, is employed at the Cardinal Stefan Wyszyński University, Department of Pharmaceutical Technology, Faculty of Pharmacy, Collegium Medicum in Bydgoszcz, Poland, and is General Secretary of Employed Pharmacist Europe (EPhEU), and as such, this author must stress that the publication was written for academic interest. E.D, M.J, and D.S are employees of the Polish Pharmaceutical Group S.A and members of the Polish Pharmacist Trade Union in Poland. Additionally, at the time of publication, E.D is a PhD candidate at the Department of Pharmaceutical Technology, Faculty of Pharmacy, Collegium Medicum in Bydgoszcz, Poland.

CRediT authorship contribution statement

Piotr Merks: Conceptualization, Funding acquisition, Methodology. Marta Jakubowska: Data curation, Writing - original draft, Writing - review & editing. Edyta Majchrowska: Data curation, Writing - original draft, Writing - review & editing. Joanna Bogusz: Data curation. Krzysztof Bilmin: Data curation, Project administration, Writing - original draft. Katarzyna Febril Sola: Data curation, Writing - original draft. Andreas May: Data curation, Writing - original draft. Anita Majchrowska: Data curation, Writing - original draft. Marko Kozol: Conceptualization, Writing - original draft. Jakub Pawlowski: Formal analysis. Milosz Jaguszewski: Formal analysis. Regis Vaillancourt: Conceptualization, Formalization.

Declaration of competing interest

The authors declare no conflict of interest.

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