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The legal extension of the role of pharmacists in light of the COVID-19 global pandemic – a review.

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Conflict of interest

The authors declare no conflict of interest.

Disclosures

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.

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1 Abstract

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

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

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

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

25 Conclusions: Novel legal extensions have allowed exploitation of the full potential of
26 pharmacists worldwide, aiding the limited resources of overloaded healthcare systems.

27
28 **Keywords:** COVID-19; pharmaceutical care, pharmacist; community pharmacies; legislation

30 Introduction

31 Pharmaceutical care is focused on the patient pharmacy practice, with the following
32 aims: to protect public health through healthy lifestyle promotion, prevention of diseases, as
33 well as assessment, initiation, and supervision of the proper course of pharmacotherapy in close
34 cooperation with the patient and, if necessary, with other healthcare professionals. In addition,
35 pharmaceutical care aims to ensure the safe and rational use of drugs to optimise the patient’s
36 health-related quality of life, achieve positive clinical outcomes, and reduce treatment costs.¹
37 Over the past four decades, the role of the pharmacist has evolved from that of medicine
38 supplier towards that of a provider of services and information, and finally - to provider of
39 patient care by actively participating in the treatment process. Increasingly, the pharmacist’s
40 task is to ensure that a patient’s drug therapy is appropriately indicated, the most effective
41 available, the safest possible, and convenient for the patient. By taking direct responsibility for
42 an individual patient’s medicine-related needs, pharmacists can make a unique contribution to
43 the outcome of drug therapy. The important role of pharmacies, which form an integral part of
44 the healthcare system, should be emphasised in the daily delivery of medicines, therapeutics,

45 vaccines, and key health services to the public. It is well known that pharmacists are among the
46 most accessible healthcare professionals; in many cases pharmacy staff are available 24 hours a
47 day. The role of pharmacies in a crisis, such as the current pandemic, is of crucial importance
48 because they are often the first and the last point of contact with the health care system for
49 patients who need reliable information and advice. Pharmacists have already confirmed their
50 important role in emergencies, including during the previous pandemics of H1N1 influenza and
51 SARS.²⁻⁴ Pharmacists play an important role in patient care during a pandemic both in
52 community pharmacies^{5,6} and in the hospital setting.⁷ Although the main focus of healthcare
53 services is to respond to COVID-19, people still have other non-COVID-19-related symptoms
54 and conditions that require professional attention.⁸ During a time of pandemic pharmacists
55 should concentrate not only on reducing the possibility of virus spread but also on patients'
56 daily needs related to taking medicines. Also, patients requiring special attention, such as after
57 haematopoietic cell transplantation or during cell therapy, can benefit from the involvement of
58 pharmacists in their therapeutic process during the COVID-19 pandemic.⁹

59
60 The special needs of community pharmacy services during the COVID-19 pandemic should
61 include the following:

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

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

86

87 **Methods**

88 Using online databases, a systematic literature review of the legal regulations related to
 89 pharmacy for COVID-19 was carried out. Key articles were retrieved mainly from PubMed
 90 and Google Scholar using the terms ‘COVID-19’, ‘2019-nCoV’, ‘coronavirus’, and ‘SARS-
 91 CoV-2’ as keywords for our search. We included scientific publications from 1 February 2019
 92 to 15 May 2020. Only publications focusing on the role of the pharmacist in the SARS-CoV-
 93 2 pandemic were eligible for inclusion. We screened all reference lists of relevant studies in
 94 order to identify any missing publications.

95

96 **Pharmacy community activities related to COVID-19: a review**

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

106

107 **Table 1.** Pharmacy community activities related to COVID-19 in different countries.¹⁰

Country	Actions
Austria	<ul style="list-style-type: none"> · 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.¹¹
Belgium	<ul style="list-style-type: none"> · Permission to denature alcohol by Belgian pharmacists.¹² · Granting exclusive authorisation for pharmacies to sell certain medical devices, individual protective equipment, and biocides, including hydroalcoholic gels and masks, with the following restrictions: <ul style="list-style-type: none"> - 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.).¹³

Canada	<ul style="list-style-type: none"> · Authorisation of pharmacists to prescribe, sell, or provide controlled substances in limited circumstances, or transfer prescriptions for controlled substances (e.g. narcotics, controlled drugs, and benzodiazepines), including the following permissions for pharmacists: <ul style="list-style-type: none"> - to extend and renew prescriptions (for periods beyond the durations prescribed by law); - to transfer prescriptions to other pharmacists; - permit practitioners to verbally prescribe prescriptions with controlled substances; - to deliver controlled substances to patients (at their homes or an alternate location). · Exemption from the obligation to provide information to the doctor aimed at "extending, adjusting, or replacing a medication", unless a doctor requests it. · The prescribing system may use e-mails to communicate prescribing directions to continue providing patient care.¹⁴⁻¹⁶
Croatia	<ul style="list-style-type: none"> · Exception procedure for dispensing medicines in short supply (replacement or substitution).^{11,17} · The Red Cross and Croatian Chamber work together to intensify home delivery of drugs to vulnerable people. Drug deliver pharmacist volunteer. · Dispensing haemophilia drugs for two months at once.¹⁸ · Implementation of e-prescription of orthopaedic aids.
Czech Republic	<ul style="list-style-type: none"> · Permission to compound antiseptic solutions.¹⁹
Finland	<ul style="list-style-type: none"> · Permission to compound hand disinfectants by pharmacies.²⁰
France	<ul style="list-style-type: none"> · Authorisation for pharmacies to prepare hydroalcoholic gels, following World Health Organisation (WHO) recommendations, if they are out of stock.²¹ · Exceptional renewal of chronic treatment by community pharmacists.²² · Launching a special code in pharmacies for victims of domestic violence.²³
Germany	<ul style="list-style-type: none"> · Temporary authorisation for pharmacies to prepare hydroalcoholic gels in pharmacies, following WHO recommendations, if they are out of stock.²⁴
Italy	<ul style="list-style-type: none"> · Decree for pharmacists to give oxygen to patients, also at home.²⁵ · Introduction of e-prescriptions.²⁶ · Medicine home delivery service to vulnerable people by Red Cross and Federfarma.²⁷ · Promoting the preparation of disinfectant products by pharmacies, also to counter speculative prices.²⁸
Netherlands	<ul style="list-style-type: none"> · Implementing remote consultations with patients (video calling,

	<p>telephone, e-mail) to ensure continuity of pharmaceutical care, using guidelines provided by The Royal Dutch Pharmacists Association²⁹</p> <ul style="list-style-type: none"> · 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.³⁰ · 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.³¹
Poland	<ul style="list-style-type: none"> · Shorter period for transferring funds to pharmacies from the National Health Fund (at the latest the day after positive verification of the documents sent by the pharmacy).³² · Permission for pharmacists to prepare ethanol antiseptic solutions for the skin.³⁰⁻³³ · 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).³⁴ · 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 moment in 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.³¹
Portugal	<ul style="list-style-type: none"> · 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.³⁵ · 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.³⁶

	<ul style="list-style-type: none"> · Protocol for pharmacist screening tests – the ANF has established a protocol with a private company, specialised in laboratory tests, which has implemented drive-thru test sites in several locations in the country. Tests will be extended to anyone with at least one symptom compatible with COVID-19.³⁷
Spain	<ul style="list-style-type: none"> · 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.³⁸ · Authorisation of community pharmacists to dispense hospital-only medicines to patients who need to take their medication in hospitals.³⁹
United Kingdom	<ul style="list-style-type: none"> · 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.⁴⁰ · Pharmadoctor eTool (an online consultation guidance and record-keeping platform) to carry out virtual consultations with patients remotely using WhatsApp, FaceTime, or Skype.⁴¹ 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.⁴²
United States	<ul style="list-style-type: none"> · Invocation of emergency pharmacist authorities to allow for pharmacist refilling.⁴³ · Creation by community pharmacies of COVID-19 testing sites.⁴¹ · 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 · Permission for pharmacists to test and initiate treatment for influenza and Group A Streptococcus.⁴⁵ · Introduction of permission for vaccine administration by a pharmacist after completing training.⁴⁵ · Extension of the rights of pharmacy technicians for permission to administer vaccines, perform remote data entry, and take new orders.⁴⁶

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

112 **Table 2.** Legal solutions for medicine shortages in European countries during the COVID-19
 113 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	✓					

114

115 Basic knowledge on COVID-19, particularly the onset symptoms and transmission
 116 routes, may be provided by pharmacists to help the community population understand the
 117 pandemic situation properly and to promote early identification of suspected individuals.⁴²

118 Discussion

119 As stated in this article, an extensive range of new responsibilities have been introduced
 120 into the community pharmacy setting to expand the role of the pharmacist in the face of the
 121 pandemic. First and foremost, pharmacists are responsible for implementing guidelines aimed
 122 at ensuring patient and staff safety. One of the most difficult parts of this task is to promote
 123 social distancing. Pharmacists should organise pharmacies in such a way as to make it difficult
 124 for the virus to spread. These actions are particularly important due to an increased number of
 125 patients, especially at the beginning of the pandemic and just after the first news on this issue
 126 had been published by the media. Temporary barriers are designed to limit the number of
 127 patients in the pharmacy at any given time and to increase the distance between patients.
 128 However, the introduction of safeguards and procedures has led to a significant financial
 129 burden. Another threat to the financial stability of a pharmacy may be its temporary closure due
 130 to lack of staff – for example, because of unexpected quarantine.⁴³

131 The most important pharmacists' tool, however, is persistent patient education on how
 132 to behave in the pharmacy and, in a broader context, how patients can protect themselves from
 133 infection. Two areas of this education should be highlighted in particular. Firstly, this education
 134 will be frequently initiated as a response to patients' questions, but it should not be limited to a
 135 simple explanation and should include other key areas of infection prevention. Secondly, it is
 136 important to inform patients that the recommendation is based on current knowledge, so it is

137 necessary to regularly update the obtained information. Forming this habit can also help to
138 improve adherence and, consequently, patient safety.

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

145 However, the fundamental role of the pharmacist is still to dispense medications. This
146 vital service is inevitably related to the profession and the place of the community pharmacy in
147 the healthcare system. Thus, the pharmacist must ensure that patients have uninterrupted access
148 to medications. The coronavirus SARS-CoV-2 pandemic, on the one hand, led to a
149 deterioration of the geopolitical situation, affecting the availability of medicines. It is worth
150 mentioning here the importance of the role of China, the first country to be hit by the
151 coronavirus, which, as a major producer of active pharmaceutical ingredients (APIs), remains
152 an important player in drug distribution.^{44,46} Secondly, the supply of medicines is hampered by
153 the significantly increased demand for medicines and food supplements at the beginning of the
154 pandemic.⁴⁶

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

167 The different set of new responsibilities is associated with compounding antiseptics.
168 Due to the temporal shortage of antiseptics, this role is an important step to minimise the
169 pandemic. This service, as summarised in this paper, has been introduced in most European
170 countries. Some services are strictly unique, e.g. French pharmacists can report the complaints

171 of female victims of domestic violence. From a historical perspective, this service represents a
172 new area of psychological intervention that can be introduced into the community pharmacy
173 and reinforce new thinking about the potential future role of pharmacists. Home-based services
174 are also implemented only if social distancing can be maintained to protect patients and
175 pharmacists from unwanted contamination.

176

177 **Conclusions**

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

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186 M.J, E.D, K.F.S, M.K, A.M., J.B, A.M, K.B - Data curation;
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188 P.M - Funding acquisition;
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193

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