Online pharmacy operations and distribution of medicines

Global Survey Report FIP Community Pharmacy Section 2021





International Pharmaceutical Federation

Community Pharmacy Section



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1 Introduction

1.1 Community pharmacy, at the heart of our communities

The International Pharmaceutical Federation (FIP) published the <u>FIP Development Goals</u> (DGs) in 2020, which are a key resource for transforming the pharmacy profession.¹ The goals align with FIP's mission to support global health through advancement of pharmaceutical sciences, practice, and education. The FIP DG 21 calls on the profession to have policies, regulations and strategies to ensure the sustainability of pharmacy practice.¹ To ensure sustainability, the profession must embrace digital transformation.² The <u>FIP DG 20</u> (Digital health) commits to enablers of digital transformation and effective processes to facilitate the development of a pharmaceutical workforce that is digitally literate.¹

The <u>FIP Community Pharmacy Section vision document</u> defines the direction for community pharmacy for the period 2020–2025, setting priorities for actions that can be implemented at national, regional and local levels.³ Importantly, it signals the intention to make the most of pharmacists' skills for the benefit of all citizens in the heart of our communities. This vision "shows how every community pharmacist can improve outcomes for their community and help build and sustain a safe and collaborative community of care that can harness exciting technological advances such as those highlighted through the One FIP forum on technology".³ The ability to harness technologies for the delivery of clinical services, provide choice and access, and improve patient care and outcomes is unique.³

1.2 Embracing digital health

Digital health has become increasingly common practice in community pharmacy.² The pharmacy sector continues to utilise technology to improve access, choice and affordability for consumers and to empower pharmacists to manage medicine risks for consumers and be more accountable and responsible for medicine safety, efficacy and overall value.² The use of digital health records, electronic prescriptions (e-prescriptions) and real-time prescription monitoring also provide opportunities for pharmacists to ensure quality and safe use of medicines.² Digital health has been focused and accelerated due to the COVID-19 pandemic. Consumers turn to the internet to retrieve health information and obtain various health services or products.

In September 2021, FIP released a <u>Statement of Policy in Digital Health.</u>⁴ The statement recommends that pharmacists "be a driving force in incorporating evidence-based digital technologies into daily practice" and "facilitate patients' digital literacy", so consumers feel empowered to make informed choices.⁴ The statement highlights that regulation of digital technologies for marketing, promotion and the purchase of medicines and medical products should be enforced.⁴ It further recommends that attention should be paid to the digitalisation of the supply chain process for its potential value in terms of preventing substandard or falsified medicines, its role in more efficient and resilient supply and further automation of pharmacists' activities.⁴ Lastly, it calls for remuneration models to enable pharmacist-led use of digital technologies for pharmaceutical care to benefit patients while ensuring sustainability.⁴

Importantly, it must be recognised that pharmacists not only provide products but also need to adapt by providing new digital services. Findings from a FIP survey published in 2021 titled "Digital health in pharmacy education: Developing a digitally enabled pharmaceutical workforce", highlighted that new digital technologies must be people-centred, high-quality, evidence-based, effective, efficient, inclusive, equitable and trustworthy in order to be integrated into practice.⁵ The report concluded that greater work on how digital health technologies can be further leveraged in community pharmacy is needed and that "lack of enabling policies and guidance, as well as lack of technical limitations and access to data" are the biggest challenges in practice.⁵

1.3 Proliferation of online pharmacies

"Online pharmacy" (also known as internet or mail-order pharmacy) is an umbrella term for retailers of non-prescription and prescription medicines that dispense or sell medicines directly to patients through the mail and provide information on their products and services via the internet. It is important to delineate the types of online pharmacies that have been identified in the published literature. These include chain pharmacies that operate online, online pharmacies that operate solely online, and brick-and-mortar pharmacies that have an online presence.^{6–8} Online pharmacies have been in existence since 1999, with Soma.com being the first pharmacy to operate online.^{9,10} However, the online pharmacy landscape has changed with rapid proliferation of online pharmacies and e-commerce, the provision of digital service offerings, and direct-to-consumer healthcare.¹⁰ This is in parallel to the increasing accessibility of medicines and health information and the availability of online consultation services.

Consumers may choose to utilise online pharmacies for a multitude of reasons, such as convenience, 24/7 accessibility, price transparency, potentially greater consumer privacy and availability of products,^{11,12} when compared with brickand-mortar pharmacies. For disabled or housebound patients who have difficulty accessing a pharmacy, the option of having medicines delivered is obvious. Consumers living in rural or remote areas, or those seeking products but who prefer anonymity, ordering medicines online also has advantages.^{11,13–15}

While online pharmacies provide increased access to medicines and services, consumers may inappropriately selfdiagnose or self-medicate, engage in medically unnecessary behaviour or substance abuse, or potentially encounter drug-to-drug interactions, contraindications or adverse effects.^{12,16} This introduces significant potential for harm to the health of consumers, termed "digital iatrogenesis" ("preventable patient harm resulting from injury that occurs from the use of information, services or products delivered or enhanced through the internet and related technologies").¹⁷ Other non-health related risks include breach of privacy, theft of personal information or fraud where products are not delivered.¹² This highlights the importance of health professionals in ensuring consumers are informed and empowered in the decision-making process.

Substandard and falsified medicines, as defined by the World Health Organization (WHO), are a major threat to public health.¹⁸ The problem has expanded in developed and developing countries, with an estimated 10.5% of medicines worldwide being substandard or falsified.¹⁸ Most of the burden falls on low- and middle-income countries because of poor pharmaceutical governance and poor supply-chain management.¹⁹ Poor-quality medicines increase risks of morbidity and mortality through adverse drug interactions, prolonged illness and heightened risk of treatment failure.²⁰ In 2013, the WHO launched the <u>Global Surveillance and Monitoring System</u> encouraging countries to report incidents of substandard and falsified medicines to assist in developing an accurate assessment of the global problem.²⁰ FIP's commitment to address this significant issue is visible through the <u>Statement of Policy on Counterfeit Medicines</u>, which highlights that pharmacists are critical in fighting substandard and falsified medicines and ensuring safety.²¹

1.4 Regulation of online pharmacies

Fittler *et al* describe legitimate online pharmacies as "websites that comply with both the laws and regulations of the country where the online pharmacy website operations occur and the destination to where the pharmaceutical products are shipped to the consumer".⁸ Online pharmacies provide access to controlled substances (according to laws and regulations of each country or jurisdiction), which in regulated systems require an original medical prescription before they can be supplied.¹² However, some online pharmacies only require an online health evaluation or completing an "online questionnaire" to supply these medicines.¹²

With the rapid proliferation of online pharmacies, there has also been an increase in illegal online pharmacies, which may inappropriately advertise the sale of prescription medicines without a valid prescription, distributing substandard or falsified medicines or filling prescriptions from "cyber doctors" who have not established a legitimate relationship with the patient or an adequate diagnosis. Illegitimate or illegal online pharmacies are defined as "pharmacies that either fail to meet national or international pharmacy regulations or have not been subjected to requisite regulatory review, and/or certification".²²

Fittler *et al* also highlight that effective regulatory oversight and enforcement regarding online pharmacies is difficult given the impalpable nature of the internet and its global dimension.⁸ Furthermore, Orizio *et al* highlight that it is difficult to determine the exact number of illegitimate online pharmacies, assess the quality and safety of the medicines or products available, and determine the volume of medicines sold and supplied online. As such, the impact on global public health is difficult to determine.¹² Orizio *et al* propose a two-level approach to enhance the benefits of online pharmacies and limit the risks which include having international laws regulating online pharmacies and increasing the health/digital literacy of individuals.¹² Pharmacists should be aware of the increasing complexity of the issues associated with online pharmacies and seek to direct individuals to legitimate websites and promote the quality use of medicines.²³

1.5 Opportunity for community pharmacies

The COVID-19 pandemic has driven a rapid shift in consumer behaviour.²⁴ Evolving consumer preferences and needs due to COVID-19 has made pharmacy e-commerce integral to healthcare delivery. With this, consumers are increasingly wanting a high level of service, convenience, innovation and personalisation. This challenges pharmacists to provide a positive face-to-face experience for consumers while also utilising digital or online channels. Survey data reported by Salesforce highlighted that 55% of consumers prefer digital channels, while 40% of respondents indicated they would not do business with a company if it was not via their preferred channel.²⁴ The data indicate that 75% of consumers expect companies to use technologies to create better experiences, and 54% believe that companies need to transform how they engage online.²⁴

The pandemic has dramatically shaped the e-commerce landscape, including in the pharmacy sector, and the demand for online services offered by pharmacies has increased in many countries. Consumers using online pharmacies can easily maintain social distancing and have their medicines delivered to their home. It is also likely that the pandemic has changed preferences for some consumers permanently and the demand should remain high in the future. Embracing digital transformation is critical and should be seen as an opportunity for brick-and-mortar pharmacies to further solidify themselves at the heart of their communities.

Importantly, payment structures are needed to support community pharmacists' role as primary healthcare providers for the delivery of pharmacy services, including engaging in technology and the delivery of services online, as a means of promoting access, choice and universality in healthcare to consumers. Community pharmacists must champion best practice, identify future needs and relevance in the delivery of care, choice, value, safety and sustainability.

This publication reports the findings from a global survey-based study on this topic.

2 Aim and methods

2.1 Aim

The aim of the study was to provide a global snapshot of online pharmacy operations and the distribution of medicines on the internet; determine how online pharmacy operations may impact patient safety; and determine the impact of online pharmacy sales (actual or perceived) on brick-and-mortar pharmacies.

2.2 Methods

Data were collected from FIP member organisations and several other invited organisations through an online global survey. This FIP survey was conducted between November 2020 and January 2021. The survey was accompanied by a letter inviting member organisations to participate, explaining the aims of the survey, as well as an informational email from the project manager explaining the study methodology.

2.2.1 Design of the survey questionnaire

The survey was developed independently by FIP in four languages (English, Spanish, French and Portuguese) and based on previous questionnaires from 2015 and 2017. The 2020 survey incorporated suggestions from member organisations and the FIP Community Pharmacy Section. The survey was developed in the online survey platform QuestionPro and, in some instances, was distributed as Microsoft Word editable forms to facilitate data collection. Accompanying the survey was a glossary of key concepts in the various languages to ensure all respondents used the same terminology to describe the situation in their respective countries. The survey and glossary are available on request from FIP (fip@fip.org).

2.2.2 Study sample

The survey and glossary were sent to 118 pharmacy organisations. As the survey aimed to collect national level data, organisations from the same country were invited to provide a single response. An analysis by WHO region and World Bank income level was provided to explore regional variations or the influence of economic factors.

2.2.3 Limitations

Despite the distribution of the survey and glossaries in four languages, the survey questions may have been interpreted differently by respondents, which may have resulted in some questions being partially or inaccurately completed. Any inaccurate information provided by any of the respondents or misinterpretation of questions may have influenced the accuracy of the results. As such, care should be taken when interpreting the findings.

Despite efforts to ensure the survey items could accommodate the complexity and diversity of the existing international pharmacy models, it may have been difficult for some member organisations to reflect their country's situation through the options available in the survey. This may also be relevant in countries with internal regulatory diversity (i.e., where regulations can vary by province, state or region). In such cases, organisations were asked to respond by considering the regulatory model that covers or affects most of the country.

Despite efforts to ensure the accuracy of the data, FIP and the CPS cannot be held responsible for inaccurate data that may have been submitted by respondents. The survey requested that the year and source of data were indicated, but this was not systematically observed by all respondents. Data sources are available on request from FIP (<u>fip@fip.org</u>).

3 Results

Here we present the survey findings regarding the regulation of the online distribution of medicines and offer insights into the implication of each regulatory system. These regulations may impact not only access to medicines, but also the degree to which patients and pharmacists interact, how medicines are selected and used, patient safety and even treatment outcomes.

3.1 Respondent characteristics

Responses were received from 79 countries, and the response rate was 67%. Table 1 provides an overview of the responses received from each WHO region. Primarily, most of the respondents were based in European countries (n=36; 46%), followed by countries in the African (n=14; 18%) and the Western Pacific (n=12; 15%) regions.

Table 1. Sample distribution per WHO region covered by the study

WHO region	Number of countries invited to participate in the study (n=118)	Responses (n=79)	Percentage of sample (%)
Africa	29	14	18
Eastern Mediterranean	11	5	6
Europe	43	36	46
The Americas	16	9	11
South-East Asia	6	3	4
Western Pacific	13	12	15
Total	118	79	100

The sample's distribution by income level is presented in Table 2. The largest proportion of responses were received from high- and upper-middle income countries (n=56; 71%). The income level groups used to present data in this report refer to the respondents that provided data. As such, the designations may not represent the entirety of those groups.

Table 2. Distribution of survey respondents, by income level

WHO region	Number of respondents (n=79)	Percentage (%)
Low income	6	8
Lower-middle income	17	21
Upper-middle income	18	23
High income	38	48
Total	79	100

3.2 Electronic prescriptions

Most countries indicated that e-prescriptions were implemented in their jurisdiction (n=45; 58%). This was highest in Europe (n=29; 64%), the Americas (n=6; 13%) and Western Pacific (n=6; 13%) (see Table 3).

WHO region	Number of respondents (n=78)	Yes (n=45)	Percentage (%)	No (n=33)	Percentage (%)
Africa	14	2	4	12	36
Eastern Mediterranean	5	0	0	5	15
Europe	36	29	64	7	21
The Americas	9	6	13	3	9
South-East Asia	3	2	4	1	3
Western Pacific	11*	6	13	5	15
Total	78	45	100	33	100

Table 3. Implementation of electronic prescriptions, by WHO region

*Missing one response from the Western Pacific region.

3.3 Shared patient health records

Most respondents indicated that community pharmacists were not able to access shared patient health records (n=45; 58%) (Table 4). However, a small proportion of countries indicated that community pharmacists had access (n=18; 23%). Countries having access included Australia, Belgium, China Taiwan, Czech Republic, Denmark, Ecuador, Hong Kong SAR China, Iceland, Italy, Japan, Republic of Korea, Mongolia, Montenegro, The Netherlands, New Zealand, Paraguay, Singapore and Turkey. However, the level of access varied between regions. Only one country, Hong Kong SAR China, indicated that community pharmacists had access (reading rights) to a patient's complete health record, with the remainder able to access only a part of the health record (e.g., medication history only). All respondents from the African and Eastern Mediterranean regions indicated that community pharmacists did not have access.

Table 4. Community pharmacists' access (reading rights) to shared patient health records, by WHO region

WHO region	Number of respondents (n=77)	Community pharmacists have access to the complete health record (n=1)	Community pharmacists have access to only a summary of the patients' health record (n=2)	Community pharmacists have access to only a part of the patient's health record (e.g., medication history) (n=15)	Community pharmacists have no access to a shared patient record (n=45)	Other (n=14)
Africa	14	0	0	0	12	2
Eastern Mediterranean	5	0	0	0	4	1
Europe	35*	0	1	7	20	7
The Americas	9	0	0	2	5	2
South-East Asia	2*	0	0	0	2	0
Western Pacific	12	1	1	6	2	2
Total	77	1	2	15	45	14

*Missing one response each from Europe and South-East Asia.

Only 10% of countries indicated that community pharmacists have writing rights in shared health records (n=8; 10.4%) (Table 5). Positive responses were mostly from the Western Pacific region. Interestingly, the majority of countries in Europe indicated that community pharmacists had reading rights but did not have writing rights.

Table 5. Community pharmacists' access (writing rights) to shared patient health records (i.e., permission to introduce or modify relevant data), by WHO region

WHO region	Number of respondents (n=18)	Yes (n=8)	Percentage (%)	No (n=10)	Percentage (%)
Africa	0	0	0	0	0
Eastern Mediterranean	0	0	0	0	0
Europe	8	2	25	6	60
The Americas	2	1	13	1	10
South-East Asia	0	0	0	0	0
Western Pacific	8	5	63	3	30
Total	18	8	100	10	100

3.4 Online distribution of medicines

Online access to non-prescription medicines (NPMs) varied among the regions. In most cases, the online supply of NPMs was via online operations of a brick-and-mortar pharmacy (n=48; 61%). Twelve countries (15%) indicated that NPMs could be purchased by consumers on online pharmacies which are not linked to a brick-and-mortar pharmacy. Other online avenues for NPMs to be purchased by consumers included generalist outlets (e.g., supermarkets) (n=20; 25%) and online non-pharmacy supply (n=16; 20%). Interestingly, 19% of countries (n=15) indicated that the online sale of NPMs is not allowed (see Table 6).

Table 6. Online access to non-prescription medicines, by WHO region

WHO region	Online operations of a brick-and- mortar pharmacy (n=48)	Online pharmacies not linked to a brick- and-mortar pharmacy (n=12)	Online non- pharmacy supply (e.g., druggists) (n=16)	Online generalist outlets (e.g., supermarkets) (n=20)	Online sales of these types of medicines are not allowed (n=15)
Africa	5	0	1	2	2
Eastern Mediterranean	0	0	0	0	2
Europe	27	4	7	8	5
The Americas	7	3	2	4	1
South-East Asia	2	2	2	2	1
Western Pacific	7	3	4	4	4
Total	48	12	16	20	15

Most countries indicated that prescription-only medicines (POMs) were only available through online operations of a brick-and-mortar pharmacy (n=32; 41%). However, 25 countries (n=25; 32%) indicated that the online sale of POMs was not allowed. The online availability of POMs through generalist (e.g., supermarkets) or non-pharmacy outlets (e.g., druggists) were not shown, except for one country in the Western Pacific region (see Table 7).

WHO region	Online operations of a brick-and- mortar pharmacy (n=32)	Online pharmacies not linked to a brick- and-mortar pharmacy (n=7)	Online non- pharmacy supply (e.g., druggists) (n=1)	Online generalist outlets (e.g., supermarkets) (n=1)	Online sales of these types of medicines are not allowed (n=25)
Africa	5	0	0	0	1
Eastern Mediterranean	0	0	0	0	2
Europe	13	4	0	0	14
The Americas	6	1	0	0	3
South-East Asia	2	1	0	0	0
Western Pacific	6	1	1	1	5
Total	32	7	1	1	25

Table 7. Online access to prescription-only medicines, by WHO region

Overall, 25% of countries (n=19) indicated that online sales of pharmacist-only medicines are not allowed. In most regions, online supply of pharmacist-only medicines only occurred if the online operations were linked to a brick-and-mortar pharmacy (n=27; 34%). The supply of pharmacist-only medicines is not commonly seen through online pharmacies not linked to a brick-and-mortar pharmacy (n=3; 3.8%), online non-pharmacy supply (n=1; 1.3%) and online generalist outlets (n=1; 1.3%) (see Table 8).

Table 8. Online access to pharmacist-only medicines, by WHO region

WHO region	Online operations of a brick-and- mortar pharmacy (n=27)	Online pharmacies not linked to a brick- and-mortar pharmacy (n=3)	Online non- pharmacy supply (e.g., druggists) (n=1)	Online generalist outlets (e.g., supermarkets) (n=1)	Online sales of these types of medicines are not allowed (n=19)
Africa	4	0	0	0	1
Eastern Mediterranean	0	0	0	0	2
Europe	14	2	0	0	8
The Americas	4	0	0	0	3
South-East Asia	1	0	0	0	0
Western Pacific	4	1	1	1	5
Total	27	3	1	1	19

Twenty-seven countries (33.8%) indicated that the online sale of specialty medicines is not allowed. For this study, specialty medicines were defined as "usually high-cost medicines which are intended for use in rare conditions, or which require special handling or ongoing clinical assessment, or a limited distribution network". Specialty medicines not requiring in-hospital administration are supplied in all regions through online outlets linked to a brick-and-mortar pharmacy (n=17; 22%), except in the Eastern Mediterranean. It was shown that these medicines are not available through online non-pharmacy (e.g., druggists) and online generalist (e.g., supermarkets) outlets in all regions. Only one country in the Western Pacific region indicated supply of these medicines via the online avenues listed (see Table 9).

WHO region	Online operations of a brick-and- mortar pharmacy (n=17)	Online pharmacies not linked to a brick- and-mortar pharmacy (n=1)	Online non- pharmacy supply (e.g., druggists) (n=1)	Online generalist outlets (e.g., supermarkets) (n=1)	Online sales of these types of medicines are not allowed (n=27)
Africa	3	0	0	0	3
Eastern Mediterranean	0	0	0	0	2
Europe	7	0	0	0	14
The Americas	3	0	0	0	4
South-East Asia	1	0	0	0	0
Western Pacific	3	1	1	1	4
Total	17	1	1	1	27

Table 9. Specialty medicines not requiring in-hospital administration, by WHO region

3.5 Laws and regulations for online pharmacies

Overall, 49% of countries (n=36) indicated that they had laws and regulations for online pharmacies, while 51% (n=37) indicated that they had no such laws (Table 10). Interestingly, 74% of European countries (n=26) indicated the existence of laws for online pharmacies. Comparatively, 92% of countries in Africa (n=12) and all countries in South-East Asia (n=3) indicated there were no laws regulating online pharmacy operations.

WHO region	Number of respondents (n=73)	Yes (n=36)	Percentage (%)	No (n=37)	Percentage (%)
Africa	13	1	3	12	32
Eastern Mediterranean	4	1	3	3	8
Europe	35	26	72	9	24
The Americas	8	3	8	5	14
South-East Asia	3	0	0	3	8
Western Pacific	10	5	14	5	14
Total	73	36	100	37	100

Table 10. Laws to regulate online pharmacies, by WHO region

Note: Six missing responses.

Twenty countries (25%) indicated that e-prescriptions are required for the supply of POMs by online pharmacies. Eleven of these countries (55%) were in Europe. Uploading an image of the prescription (n=13; 16%) and the delivery of the prescription to the online pharmacy (n=7; 9%) is more common in The Americas and the Western Pacific region, respectively. Automatic questionnaires completed by patients to obtain POMs are only available in a small number of countries in Europe and The Americas (n=6; 8%). Additional requirements were reported in all regions, except South-East Asia (see Table 11).

WHO region	Electronic prescriptions (n=20)	Uploading images of prescriptions (n=13)	Delivery of prescription to online pharmacy (n=7)	Automatic questionnaires filled by patients (n=6)
Africa	0	3	0	0
Eastern Mediterranean	0	0	0	0
Europe	11	0	2	4
The Americas	3	5	1	2
South-East Asia	2	2	1	0
Western Pacific	4	3	3	0
Total	20	13	7	6

Table 11. Requirements of online pharmacies to supply prescription-only medicines, by WHO region

Sixteen countries (29%) indicated that online pharmacies can verify a prescriber from a list of registered practitioners in their country. This was more commonly seen in Europe. The majority of countries (n=33; 59%) indicated there were other systems to verify the authenticity of prescriptions for supply by online pharmacies (see Table 12). Other methods included the onus being on the pharmacist, using national health insurance or a combination of systems (n=33).

Table 12. Systems to verify the authenticity of prescriptions by online pharmacies, by WHO region

WHO region	Number of respondents (n=56)	Onus is on the consumer (n=7)	Verify from list of registered practitioners (n=16)	Other (n=33)
Africa	9	3	1	5
Eastern Mediterranean	2	0	0	2
Europe	25	1	10	14
The Americas	8	2	3	3
South-East Asia	2	0	1	1
Western Pacific	10	1	1	8
Total	56	7	16	33

Note: Twenty-three missing responses.

Overall, 21 countries (38%) indicated that there is no established method to verify the authenticity of online pharmacies, while 19 (34%) indicated that consumers could verify an online pharmacy from a list of registered pharmacies in their country. Only a small number of European countries (n=4; 7%) indicated that a special authentication website was available (see Table 13). Twelve respondents indicated methods that included identification by their licence (n=3), by their brick-and-mortar pharmacy/business address (n=3), by a logo (n=2), or through a provincial pharmacy regulatory body (n=1). The remainder did not specify (n=3).

Table 13. Identification of legal websites for online sale of medicines, by WHO region

WHO region	Number of respondents (n=56)	Verify from list of registered online pharmacies (n=19)	There is no established method to verify authenticity of online pharmacies (n=21)	There is a special authentication website for online pharmacies (n=4)	Other (n=12)
Africa	8	1	5	0	2
Eastern Mediterranean	1	0	1	0	0
Europe	31	14	7	4	6
The Americas	6	1	2	0	3
South-East Asia	2	0	2	0	0
Western Pacific	8	3	4	0	1
Total	56	19	21	4	12

Note: Twenty-three missing responses.

The majority of countries (n=41; 80%) indicated that it is a mandatory requirement for an online pharmacy to have a physical address (see Table 14).

Table 14. Mandatory requirement for an online pharmacy to have a physical address, by WHO region

WHO region	Number of respondents (n=51)	Yes (n=41)	No (n=4)	Online pharmacies are not allowed (n=3)	Don't know (n=3)
Africa	8	5	1	0	2
Eastern Mediterranean	1	0	1	0	0
Europe	27	26	0	1	0
The Americas	7	4	1	1	1
South-East Asia	2	0	1	1	0
Western Pacific	6	6	0	0	0
Total	51	41	4	3	3

Note: Twenty-eight missing responses.

Twenty-three countries (40%) indicated that there are no regulations for discounting on medicines for online pharmacy operations. By comparison, 16 countries (28%) indicated that there are regulations in place for discounting on medicines by online pharmacies, primarily from Europe. Interestingly, 19 countries (33%) indicated they "Can't say" if there are regulations in their region for discounting on medicines via online pharmacies (see Table 15).

Table 15. Regulation of discounting on medicines by online pharmacies, by WHO region

WHO region	Number of respondents (n=58)	Yes (n=16)	No (n=23)	Can't say (n=19)
Africa	9	1	3	5
Eastern Mediterranean	4	0	1	3
Europe	27	11	11	5
The Americas	8	2	3	3
South-East Asia	3	1	2	0
Western Pacific	7	1	3	3
Total	58	16	23	19

Note: Twenty-one missing responses.

The majority of countries (n=39; 65%) indicated that they "Can't say" whether there are cases of legal action against online pharmacies for the supply of POMs without a valid prescription or checking authenticity (see Table 16).

Table 16. Cases of legal action against online pharmacies for the sale of prescription-only or restricted medicines without prescriptions or checking authenticity, by WHO region

WHO region	Number of respondents (n=60)	Yes, quite often (n=6)	Rarely (n=15)	Can't say (n=39)
Africa	9	0	0	9
Eastern Mediterranean	3	0	0	3
Europe	29	5	7	17
The Americas	8	1	3	4
South-East Asia	2	0	2	0
Western Pacific	9	0	3	6
Total	60	6	15	39

Note: Nineteen missing responses.

Overall, 45% of countries (n=27) indicated that there are regulations around online pharmacies advertising a discount on medicines. Most respondents were from Europe (n=18; 58%). Half of the countries in African (n=5) indicated there are no regulations on advertising discounts on medicines by online pharmacies (see Table 17).

Table 17. Regulation of advertising discounts on medicines by online pharmacies, by WHO region

WHO region	Number of respondents (n=62)	Yes (n=27)	No (n=19)	Can't say (n=16)
Africa	10	1	5	4
Eastern Mediterranean	3	0	1	2
Europe	31	18	7	6
The Americas	8	5	1	2
South-East Asia	2	1	1	0
Western Pacific	8	2	4	2
Total	62	27	19	16

Note: Seventeen missing responses.

Most of the countries (n=47; 73%) indicated that international online pharmacies are not allowed to sell NPMs in their countries. Most respondents in Africa (n=11; 92%), South-East Asia (n=2; 100%) and the Eastern Mediterranean (n=4; 100%) regions indicated that international online pharmacies were unable to sell NPMs to national consumers (see Table 18).

Table 18. International online pharmacies allowed to sell non-prescription medicines to national consumers, by WHO region

WHO region	Number of respondents (n=64)	Yes (n=17)	No (n=47)
Africa	12	1	11
Eastern Mediterranean	4	0	4
Europe	30	11	19
The Americas	7	2	5
South-East Asia	2	0	2
Western Pacific	9	3	6
Total	64	17	47

Note: Fifteen missing responses.

Fifty countries (83%) indicated that the sale of POMs by international online pharmacies to national consumers is not allowed (see Table 19).

WHO region	Number of respondents (n=60)	Yes (n=10)	No (n=50)
Africa	12	1	11
Eastern Mediterranean	3	0	3
Europe	29	5	24
The Americas	6	2	4
South-East Asia	2	0	2
Western Pacific	8	2	6
Total	60	10	50

Table 19. International online pharmacies allowed to sell prescription-only medicines to national consumers, by WHO region

Note: Nineteen missing responses.

3.6 Other services offered by online pharmacies

Respondents were asked "Are online pharmacies offering other services like telepharmacy, e-prescriptions, apps, triage or something else?". Most countries (n=29; 63%) indicated that online pharmacies do not offer additional services, while 17 (37%) indicated that online pharmacies are offering other services. These include apps (n=4; 24%), e-prescriptions (n=4; 24%), online consultations (n=2; 12%), home delivery with follow-up (n=1; 6%) and prescription reminder services (n=1; 6%) (see Table 20).

Table 20. Other services offered by online pharmacies

Type of service	Number (n=17)	Percentage (%)
Apps	4	24
e-prescriptions	4	24
Telepharmacy	3	18
Online consultations	2	12
Home delivery with follow-up	1	6
Prescription reminder services	1	6
Other	2	12
Total	17	100

3.7 Strengths and weaknesses of online pharmacies

Respondents indicated there are several advantages of online pharmacies, the most common being increased access for patients (n=10; 25%), convenience (n=9; 23%), reduced cost for patients (n=4; 10%) in addition to improved access to medicines for isolated and rural populations (n=3; 7%). Table 21 summarises the advantages of online pharmacies based on open-ended responses. Other responses (n=8; 20%) included access to a wide range of products (n=1), enhancing pharmacy brands (n=1), customer comfort (n=1), easing work (n=1), facilitating communication with a patient in person (n=1), enhancing patient care (n=1), increasing access and choice in a pandemic (n=1) and providing more opportunity for community pharmacy (n=1).

Table 21. Summary of the advantages of online pharmacies

Advantages	Number (n=40)	Percentage (%)
Increased access for patients	10	25
Convenience	9	23
Reduced costs for patients	4	10
Improved access to medicines for isolated populations e.g., rural populations	3	8
Reduced investment in brick-and-mortar structures	2	5
Increase in the volume of sales	2	5
Time saving	2	5
Others	8	20
Total	40	100

Respondents indicated that the strengths favouring online pharmacies included access to sufficient internet services (n=7; 18%), availability of adequate information technology (IT) infrastructure (n=6; 16%), availability of a sufficient shipping/courier service (n=5; 13%), and familiarity of consumers with online shopping (n=5; 13%). Table 22 summarises the strengths of online pharmacies based on open-ended responses. Other strengths (n=8) included an increase in dispensing of POMs, an increase in market share, digital transformation from pharmacies to the online environment, improved consumer access after hours and ease of access for consumers.

Table 22. Strengths favouring participants' countries to start or sustain online pharmacies

Strengths	Number (n=38)	Percentage (%)
Sufficient internet services	7	18
Availability of adequate IT infrastructure and facilities	6	16
Availability of sufficient shipping/courier systems	5	13
Familiarity of consumers with online services e.g., e-commerce and online shopping	5	13
Reputable pharmacy chain	2	5
Large/growing clientele	2	5
Population demographics (i.e., higher income)	2	5
Improved payment systems	1	3
Others	8	21
Total	38	100

Respondents from most countries indicated that lack of counselling (n=8; 12%) and lack of face-to-face contact with patients (n=7; 11%) were the most common weaknesses of online pharmacies. Limited or lack of regulation (n=5; 8%), cyber-security threats (n=5; 8%), logistics (i.e., for the safe and timely delivery of medicines) (n=5; 8%), access to substandard or falsified medicines (n=4; 6%), increase in self-medication (n=3; 5%) and reduced quality of care (n=3; 5%) were also identified. Table 23 summarises the weaknesses of online pharmacies based on open-ended responses.

Table 23. Weaknesses of online pharmacies

Weaknesses	Number (n=66)	Percentage (%)
Lack of proper counselling	8	12
Lack of face-to-face contact	7	11
Lack of regulations	5	8
Cybersecurity threat	5	8
Logistics (safe and timely delivery of medicines)	5	8
Digital access/literacy for both patients and pharmacists	4	6
Access to substandard or falsified medicines	4	6
Access to sufficient internet connection	4	6
Patient safety implications (e.g., drug interactions, adverse drug reactions, overdose)	4	6
Professional issues (e.g., inappropriate advertising, loss of jobs and reduced public trust)	4	6
Reduced quality of care	3	5
Inappropriate self-medication	3	5
Lack of dedicated e-prescription platform	2	3
Lack of human resources	2	3
Others	6	9
Total	66	100

3.8 Strategies to start or improve online pharmacy sales

Respondents indicated that the strategy to commence or increase sales by online pharmacies in individual countries included the development of regulations or guidelines for online pharmacies (n=9; 50%), digital transformation (n=5; 28%) and increasing consumer health literacy (n=2; 11%). Table 24 summarises the strategies to start or improve online pharmacy sales based on open ended responses.

Table 24. Strategies to start or improve online pharmacy sales

Strategies	Number (n=18)	Percentage (%)
Development of guidelines or regulations for online pharmacy	9	50
Digital transformation	5	28
Increasing consumer health literacy	2	11
Others	2	11
Total	18	100

3.9 Impact of online pharmacies on brick-and-mortar pharmacies

Overall, 46% of countries (n=31) either strongly agreed or agreed that online pharmacies are a threat to brick-and-mortar pharmacies, while only 7.5% (n=6) disagreed (see Table 25).

WHO region	Number of respondents (n=67)	Strongly agree (n=9)	Agree (n=22)	Neutral (n=15)	Disagree (n=6)	Can't say (n=15)
Africa	12	2	4	2	0	4
Eastern Mediterranean	3	1	0	0	0	2
Europe	32	4	11	7	4	6
The Americas	8	1	2	4	0	1
South-East Asia	2	1	0	1	0	0
Western Pacific	10	0	5	1	2	2
Total	67	9	22	15	6	15

Table 25. Online pharmacies as a threat to brick-and-mortar pharmacies, by WHO region

Note: Twelve missing responses.

Qualitative responses included:

- Not all online pharmacies present the same level of threat. The largest threat now is perceived from larger online vendors (such as Amazon).
- Online pharmacies would mean a lot of brick-and-mortar pharmacies, especially in rural areas, would be endangered. Patients could be at risk if a pharmacist is not involved in delivering the medicine.
- We have a good community pharmacy network; it is accessible and open long hours. Although COVID-19 has changed the behaviour of pharmacy consumers, we can see that people are using online pharmacy services.
- Online pharmacies are taking away the one-on-one conversation between a pharmacist and patient, which may be impacting the quality of care being provided.
- Online pharmacies are both a threat and an opportunity, depending on where brick-and-mortar pharmacies are located. In rural areas, online pharmacy is a possibility because of long distances between the consumers and their community pharmacy. Online pharmacies are owned by brick-and-mortar pharmacies, however those with a greater online presence are still a threat.
- The online sale of POMs is permitted in Germany and online pharmacies often offer discounts on medicines. A new law has forbidden the discounts for the statutory insured. From 1 January 2022, e-prescription becomes mandatory, which makes it easier to transmit a prescription to online pharmacies via a smartphone. This could significantly increase the share of online pharmacies in the POM segment.
- The convenience offered by online pharmacies may lead to consumers preferring them to brick-and-mortar pharmacies.
- Some brick-and-mortar pharmacies are concerned about greater buying power of some online pharmacies, operating not only in Italy, but also in other European countries.
- Online pharmacy should be conducted to complement face-to face pharmaceutical consultation.
- Many independent/small chain pharmacies see online pharmacies as a threat, but chain pharmacies consider it to be an area of expansion due to the requirement that all pharmacies require a brick-and-mortar premises.
- Online pharmacies will not be a threat (in the US) because now only those with brick-and-mortar pharmacies with an [Food and Drug Administration] license can operate online pharmacies.
- Online pharmacies are important in accessing medicines, especially for isolated populations. At the same time, they present problems from the point of view of safety and pharmaceutical advice. If legislation changes and large operators enter the market it will a concern. However, the sector bets on proximity to the patient, and this aspect has gained even more importance with the pandemic and the greater need to reach people.

3.10 Risks of online pharmacy sales for patient safety

Overall, 25% of countries indicated that there are cases of irresponsible or inappropriate self-medication by consumers who have purchased medicines through online pharmacies (n=16) (see Table 26).

WHO region	Number of respondents (n=64)	Yes, quite often (n=16)	Rarely (n=6)	Other (n=7)	Can't say (n=35)
Africa	9	1	0	2	6
Eastern Mediterranean	3	0	1	0	2
Europe	31	9	4	1	17
The Americas	9	2	0	3	4
South-East Asia	2	1	0	0	1
Western Pacific	10	3	1	1	5
Total	64	16	6	7	35

Table 26. Irresponsible self-medication following the online purchase of medicines, by WHO region

Note: Fifteen missing responses.

Major patient safety risks associated with the online sale of medicines were identified by respondents. These included the supply of substandard or falsified medicines (n=9; 18%), delivery errors or storage conditions during transit (n=8; 16%), cybersecurity threats (n=7; 14%), limited patient counselling (n=6; 12%) and the sale of unauthorised or prohibited medicines (n=5; 10%). Other patient safety concerns included lack of access to patient health records (n=2; 4%) or risks amplified for consumers with low health literacy (n=2; 4%) (see Table 27).

Table 27. Risk of online pharmacy sales for patient safety

Risks	Number (n=49)	Percentage (%)
Sales of substandard or falsified medicines	9	18
Logistics (e.g., dispensing errors, delivery errors, storage conditions during transit)	8	16
Cybersecurity threat (e.g., illegal pharmacies, fraud, health data protection)	7	14
Limited patient counselling	6	12
Sales of unauthorised or prohibited medicines	5	10
Irrational use of medicines, drug abuse or misuse	4	8
Lack of access to patient health records	2	4
Low consumer health literacy	2	4
Others	6	12
Total	49	100

4 Discussion

Community pharmacy practice has evolved with the implementation of services including medication management, medication reconciliation, antimicrobial stewardship and others aimed at promoting the quality use of medicines and improving clinical outcomes. However, lack of access to digital health records is a barrier to an effective contribution by community pharmacists to achieve optimal patient care. The results revealed that community pharmacists in most countries do not have access (reading or writing rights) to digital health records, which can include clinical information such as medical history or indications for prescribed medicines, pathology and imaging results. Evidence indicates that community pharmacists with the ability to access digital health records provide more comprehensive reviews, better identification of medication-related issues and strengthened clinical recommendations.²⁵ Jackson & Peterson highlight that digital health records "facilitate the delivery of safe, efficient and effective care while connecting different points of the health system so that information can be shared securely", in addition to reducing the risk of adverse events or medication errors.²⁶ Several challenges with respect to accessing digital health records specific to community pharmacy practice have been identified, including compatibility with pharmacy workflow and interoperability with softwares.^{27,28} For evident reasons, pharmacists having access to digital health records and other information is especially critical if a medicine is sold on the internet. As an example, community pharmacists in Sweden review all sales of POMs (online as well as in brick-and-mortar pharmacies) using an Electronic Expert System (EES).²⁹ The EES assists pharmacists with the identification and resolution of medicines-related problems prior to dispensing.²⁹

The global survey highlighted that most countries had implemented e-prescriptions. This was highly reported in Europe, the Americas and the Western Pacific, while implementation in Africa, the Eastern Mediterranean and South-East Asia was lagging. Electronic prescribing is important to enhance the quality of the prescribing process³⁰ and has resulted in fewer prescribing and medication errors.³⁰ Additional benefits include greater choice for consumers, streamlining the clinical workflow, limiting exposure to infectious diseases, and removing the handling and storing of physical paper prescriptions.^{30,32} Despite the benefits, many barriers to implementation persist, the main one being the cost.^{30,33}

The global survey highlighted that online supply of NPMs is via the online operations of a brick-and-mortar pharmacy in most countries. In other regions, consumers can access NPMs through druggists or generalists, while online sale is prohibited in other regions. The availability and sale of these medicines through online pharmacies not linked to a brick-and-mortar pharmacy or other avenues raises concerns, particularly around the lack of access to professional advice and counselling by a pharmacist. The sale of medicines via the internet also promotes self-medication practices (be they appropriate or inappropriate), which has implications for patient safety and the quality use of medicines. NPMs are often perceived as being safer than POMs.³⁴ However, many are known to contain potent pharmacological agents. These medicines have the potential for adverse effects and frequent or continued inappropriate use can be clinically unsafe.^{35–38}

Community pharmacists have an important role in ensuring responsible self-medication and the provision of evidencebased information.³⁹ The FIP report "<u>Pharmacy as a gateway to care: Helping people towards better health</u>" highlights the importance of informed and responsible self-medication and states that "pharmacists and pharmacy staff are in a position to appropriately facilitate self-medication decision-making by consumers".³⁹ Pharmacists have a critical role in ensuring responsible self-medication practices and purchasing medicines via safe and reputable websites.³⁹

Approximately half of all countries indicated that there are regulations in place for online pharmacy operations ensuring accountability. The European region reported the highest percentage of jurisdictions with regulations in place. The lack of regulation or lack of enforcement of regulation creates an avenue for illegal online pharmacies and may impact the overall quality of medicines and services offered to consumers. The risks include supply to customers of substandard or falsified medicines with unknown safety and efficacy; failure in supply-chain protocols, which can impact the quality of a medicine, e.g., storage, inappropriate supply of controlled substances or narcotics; and a lack of professional advice or medicines information.

Less than half of all countries indicated that their region has no established method to verify the authenticity of online pharmacies or that consumers could verify an online pharmacy from a list of registered pharmacies in their countries. For example, in the United States (US), a way to verify the authenticity of an online pharmacy is to look for the <u>National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) Seal</u>.⁴⁰ This seal indicates that an online pharmacy has met state licensure requirements and is safe. Online pharmacies in the United Kingdom (UK) are required to follow the guidance by the General Pharmaceutical Council (GPhC) in its "<u>Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet</u>".⁴¹ The guidance seeks to ensure that

consumers obtain medicines from online pharmacies that are clinically appropriate and sets out expectations for online pharmacies.⁴¹ Similarly, European Union countries use a common logo for legally operating online pharmacies as a way for consumers to determine the authenticity of online pharmacies.⁴²

Laws on online pharmacies provide clarity to the online pharmacy segment operating in a regulatory grey area in many countries. Measures such as well-defined safety and quality benchmarks, a verifiable physical address and access to a licensed pharmacist are important. Reforms to the overall regulation of online pharmacy are needed to realise the benefits of online pharmacies. Possible important factors are reforms in terms of entry, ownership, and price regulation. Online pharmacies offer great potential for the provision of pharmacy services in a way that is more efficient. Regulation should facilitate this, also for existing brick-and-mortar pharmacies that wish to operate digitally.

The emergence of COVID-19 has aptly illustrated the huge potential for online pharmacies. Online pharmacies improve the supply of medicines by circumventing some of the limitations of the system, based on brick-and-mortar pharmacies. If the pandemic brings a permanent behavioural change among consumers, we can predict that the importance of online pharmacies will grow in the future. That is not to say that online pharmacies would completely substitute brick-andmortar pharmacies, even in the long run. However, online pharmacies widen consumer choice and may consequently improve the welfare of consumers who wish or need to obtain their medicines by means other than visiting a brick-andmortar store. Although COVID-19 has clearly increased the importance of online pharmacy markets, their development should not come at the cost of reduced service quality for consumers not using online services. Nevertheless, the COVID-19 crisis has shown the importance of having multiple distribution channels for medicines. Thus, besides fostering competition, online pharmacies can enhance the supply security of medicines.

From the perspective of competition and consumer authorities, regulation for online pharmacies should be developed ensuring well-functioning online pharmacy markets, improving consumer welfare and guaranteeing consumer safety in purchasing medicines. Both consumer protection and competition law are central to this development. However, it is important to ensure that regulation does not hamper innovation in a sector that is still developing in many countries.

5 Conclusion

The <u>FIP Community Pharmacy Section vision document</u> highlights that the COVID-19 pandemic has shown how quickly healthcare and the pharmacy profession can adapt.³ It highlights the services that pharmacists and pharmacy teams provide to their communities and their important contribution towards easing the enormous strain being placed on the global health system.³ In some countries, such as Ireland, pharmacists are the most trusted health professional,⁴³ and pharmacists have an opportunity to emerge from the pandemic with clearer priorities and innovative means to provide better healthcare and support responsible self-care.³ Through the four cornerstones of medicines supply — review, prescribe, dispense and administer — pharmacists are ready to provide more value, harness new technologies and offer more choice for consumers.³

While brick-and-mortar pharmacies are increasingly facing competition as online pharmacies become more prominent, it is important that community pharmacies embrace technology and further solidify their role as medicines experts at the heart of their communities. With appropriate regulation and remuneration models, brick-and-mortar pharmacies can adapt as needed. Effective programmes of public education to promote consumer awareness should be established while legislative reforms may be necessary to ensure online pharmacy practice and advertising of medicines is regulated. Implementation of methods to verify the authenticity of online pharmacies (e.g., logos, seals), such as those seen in the European Union, the US or the UK should also be considered in other regions. Pharmacists should contribute to patient safety by actively participating in the fight against substandard or falsified medicines.

This report calls for increased cooperation between countries in developing regulation of on line pharmacies in addition to tackle the possible challenges that the sector faces. Cooperation is imperative, particularly if cross-border operations of online pharmacies become increasingly commonplace in the future. However, competition authorities alone cannot achieve this goal, as pharmacy markets are primarily regulated by sector-specific regulators. Consequently, cooperation must be enhanced between different regulators within each country as well as at a global level.

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