LESSONS FROM THE COVID-19 PANDEMIC

Regulation of e-Commerce of Non-prescription Medicines

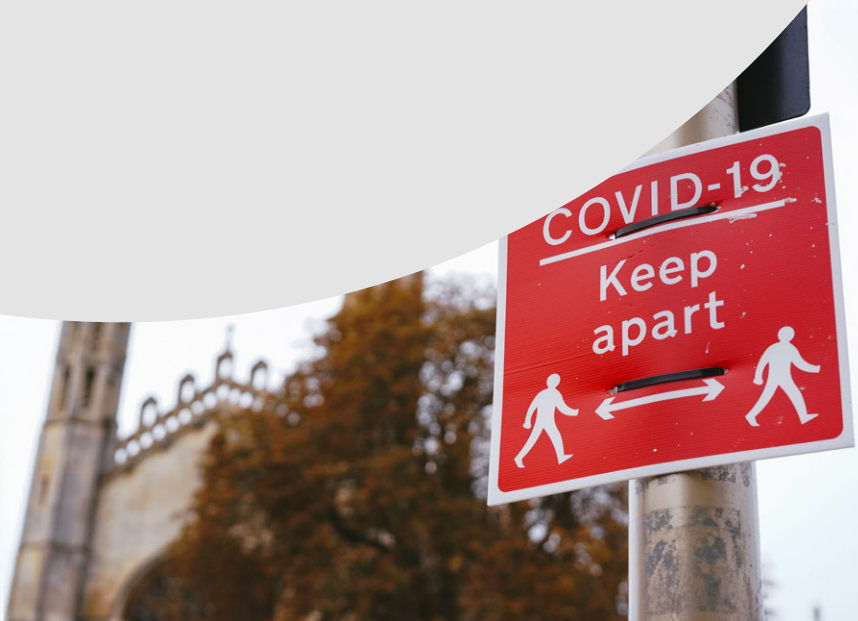
GLOBAL SELF-CARE FEDERATION

INTRODUCTION

The emergence of COVID-19 had a massive direct impact on human health in every region and country. The disease itself posed extraordinary challenges to healthcare systems from prevention to testing to treatment. It also exposed broader fragilities in the delivery of the entire range of healthcare services and products. For much of the COVID-19 crisis, primary care resources were overburdened, and many providers were inaccessible to the public due to in-person care challenges. Added to this was government efforts to limit in-person exposures by encouraging social distancing.

These factors have led consumers to turn to self-care to maintain good health, treat the symptoms of COVID-19, and to manage other self-diagnosable and treatable conditions. Moreover, to better manage their own health while seeking to respect social distancing recommendations, they increasingly utilized e-commerce to access self-care[1] solutions such as non-prescription medicines, dietary supplements, vitamins, and simple medical devices and tests designed for home use. On a global level, surveys[2,3,4,5,6,7,8,9], increasing number of visits to e-pharmacy sites[10], and actual sales in 2020[11] demonstrate an increased interest in self-care, a greater willingness to ask for advice from pharmacists, and a significant growth in e-commerce non-prescription medicine sales that has continued into 2021.

It seems clear that during the COVID-19 pandemic consumers gained increased confidence in and reliance on self-care and became more comfortable using the digital tools which support the use of self-care products, including non-prescription medicines. Research suggests that even though consumers look forward to a return to brick-and-mortar retailers, the boost in e-commerce of non-prescription medicines is not likely to revert to the pre-pandemic levels. For example, US-based research published by McKinsey demonstrates that the internet sales of OTCs were in the highest category of anticipated on-line growth in purchasing; at an expected increase of 44% post- COVID-19.[12] Overall, according to Sam Gagliardi, Executive Vice President of IRI, these reactions to COVID-19 have "accelerated the e-commerce market by 10 years in 3-6 months."[13]



BROADER RECOGNITION AND REGULATION OF E-COMMERCE OF NON-PRESCRIPTION MEDICINES

BACKGROUND

Bricks-and-mortar retail remains an important purchasing channel for consumers who prefer a hands-on purchasing experience and the wide availability of a face-to-face professional interaction. However, for a rapidly increasing set of consumers, e-commerce of non-prescription medicines is preferred as it offers several distinct benefits. Certainly, during the pandemic, e-commerce served as a good alternative to a regular model as consumers sought to maintain social distancing guidelines. More broadly, e-commerce also allows for increased access to a wider array of products across many more purchasing sites. It offers greater convenience, time savings and provides access for consumers who may not have easy geographic or physical access to a pharmacy; as well as guarantees 24x7 availability of information sources and purchasing. It creates an opportunity to generate new and usable pharmacovigilance data (i.e., real-world evidence/ data). Finally, in many instances, e-commerce of non-prescription medicines allows consumers to easily compare prices leading to lower costs to the consumer and is a preferred purchasing channel for many demographics.[14] Overall, e-commerce of non-prescription medicines is a critical tool in increasing health literacy, expanding access, and ultimately, empowering consumers to play a more active role in their own healthcare.

Sales of non-prescription medicines via e-commerce were growing prior to the COVID-19 pandemic as consumers were becoming more comfortable with all forms of on-line purchasing. However, adoption of e-commerce for non-prescription medicines has been hindered due to pre-existing regulatory barriers ranging from complete bans of on-line sales of non-prescription medicines in some markets to variable approaches in others. Those variables referred to the categories of products that can be sold online, entities which can sell a specific product class, and requirements for e-pharmacies to have a bricks-and-mortar presence. In addition, in many regions of the world, there is little to no regulatory policy or guidance focused on cross-border e-commerce and mutual recognition. Furthermore, many regulatory authorities had not yet turned their attention to the differences between the consumer purchasing experience in the e-commerce environment (the "digital shelf") versus the traditional brick-and-mortar experience. This was intensified by a lack of trust by consumers as they encountered unreliable purchasing platforms and information sources.

During the pandemic, many governments and regulatory authorities implemented several policies specifically designed to aid consumers in their efforts to purchase non-prescription medicines via e-commerce. Post-pandemic, GSCF believes that governments and regulatory authorities have the opportunity to support the safe growth of on-line purchasing of non-prescription medicines by making permanent some of the policy and regulatory changes approved during the pandemic. They could also implement best practices that have served to protect and empower consumers as they turned to the digital shelf for their non-prescription medicine needs. By doing so, whether a consumer prefers to shop on-line or continue to take advantage of in-person shopping at the pharmacy, their needs will be met safely.

DISCUSSION

Prior to 2020, many markets either did not allow or severely restricted, on-line sale of non-prescription medicines. However, in the interest of serving consumers during the pandemic, regulatory authorities in some markets, including Russia[15], India[16], and Argentina[17], either temporarily or permanently expanded opportunities for consumers to shop for non-prescription medicines via e-commerce. Also, despite changes adopted during COVID, many countries continue to maintain restrictions as to where and by whom certain non-prescription medicines can be sold. This typically involves conditions of sale such as limiting some non-prescription medicines to pharmacy-only and, in some instances, restrictions on the ability to advertise to consumers—a crucial source of information on the product. On the other hand, some regulatory authorities, such as those in the UK, Colombia, Brazil, and Mexico,[18] have maintained their product classification system, but have adapted their policies to allow on-line sales of all non-prescription medicines, at least within specified sales channels. In the UK, for instance, only registered ePharmacies can sell Pharmacy-only medicines.[19] Other online retailers can offer only General Sale products. In another example, Australia and Singapore allow only pharmacies and drugstores with physical stores and a qualified pharmacist to perform sales over the internet or by phone.[20] With these examples in mind, GSCF supports efforts by regulatory authorities to **develop frameworks that enable the growth of e-commerce by introducing risk appropriate approaches specific to the particulars of e-commerce** versus traditional brick-and-mortar retail.

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Another challenge for regulatory authorities is ensuring that consumers do not receive unauthorized or counterfeit non-prescription medicines purchased from untrusted sites. **GSCF supports efforts by regulatory authorities to bolster consumer confidence in e-commerce through secured systems and platforms**. There are several examples of authorities being pro-active in this regard. For instance, the US has two voluntary verification schemes in place, with the industry generally self-regulating.[21] In the EU there is an obligation to display the EU logo to verify whether an e-commerce store is trustworthy; by clicking on the logo, the consumer is sent to the website of the national regulator.[22] Australia, Brazil, and Mexico all require e-commerce stores to register with regulatory authority.[23]

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Secure purchasing systems and platforms rely on the availability and recognition of trusted sources of information to support consumers as they self-diagnose and make treatment decisions on-line. In other words, as they browse the digital shelf. Many countries do not, as of yet, have any robust guidelines or standards protecting or directing consumers as they shop on-line for non-prescription medicines. Among the countries that has acted in this regard is Australia, which has a “one-click away” guidance for e-advertising that facilitates consumer access to the

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fully approved electronic product label or leaflet, sometimes known as e-Product Information (ePI). ePIs have some significant advantages over their physical counterparts. First, electronic labelling can be rapidly updated to reflect the most up-to-date version of the patient leaflet, even for products bought a long time ago. Not only are ePIs more environmentally friendly, but they also allow for an increased accessibility through advanced functions such as flexible font sizes and "read loud" capability. More importantly, this and other digital regulated information, for example regulatory authority oversight of consumer health information and diagnosis apps that are found in some countries,[24] can be easily integrated into digital pathways so that consumers can make better informed choices. In addition, regulatory authorities can go beyond electronic labelling and either provide the information itself or validate trusted information sources. A good example of this is the effort undertaken by the South Africa Health Products Regulatory Authority (SAHPRA) to build an on-line directory of on-prescription medicines to help consumers access reliable information.

Another challenge facing consumers as they browse the digital shelf is the lack of a human intermediary to guide product selection and supplement digital information when needed. However, telehealth innovations emerging in e-commerce can now effectively substitute for in-person pharmacist interactions. For instance, a recent report by AESGP, 'Association Européenne des Spécialités Pharmaceutiques Grand Public' (fr), the European self-care trade association, noted that the COVID-19 pandemic drove an increase in on-line professional consultations and that it foresees "a future where more and more (physician and pharmacist) consultations will happen online."[25].

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GSCF believes that a significant step forward in supporting consumers as they turn toward e-commerce purchasing of non-prescription medicines is for regulatory authorities to **develop guidance or standards on how information should appear to consumers as they browse the digital non-prescription medicines shelf**. This includes **guidance around trusted data sources and support from telemedicine**.

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Related to the availability of trusted and reliable information sources is e-advertising undertaken by manufacturers and retailers. While misleading e-advertising could undercut consumer confidence in on-line purchasing, its regulation varies significantly from country to country. **GCSF believes that there is an opportunity for the non-prescription medicines industry to adopt self-regulatory standards and practices,** that are backed up by **post-market controls from regulatory authorities**. The self-care industry in Australia and the UK are prime examples of effective self-regulation schemes. On the other hand, the recent US FDA warning letter against Amazon offers an illustration of how regulatory authorities can step in when abuses are identified.[26]

Another hurdle to e-commerce in some markets is the breadth of products available for sale. A solution to this could come in the form of cross-border sales and mutual recognition, similar to what is available in the European Union. **GSCF believes that there is an opportunity for greater clarity, consistency, and conformity in the regulation of cross-border e-commerce of non-prescription medicines, including mutual recognition among regulators,** or clearer positions or guidance on cross-border sales in order to both increase the variety of choices available within a nation and to enable access across borders.

CONCLUSION

During the COVID-19 pandemic, consumers across the globe turned increasingly toward self-care, not only to manage the mild to moderate symptoms of COVID-19, but also to diagnose and treat other conditions and to maintain general wellness. In addition, consumers, faced with restrictions on public engagement, gradually turned to on-line purchasing for their self-care needs, including non-prescription medicines, without any identifiable impact on safety. Empowering and facilitating consumers in their self-care efforts have well-established benefits to individuals and to health systems. Governments and nongovernment organizations should undertake additional efforts to empower consumers to increase their use of non-prescription medicines. Importantly, regulatory authorities should seek to implement policies that accommodate e-commerce practices that that are different than those associated with its bricks-and-mortar counterpart, thus empowering consumers as they shop the digital shelf.

It is also worth noting that a robust e-commerce market is based on two fundamental pillars—an environment that encourages and facilitates consumers to take a more active role in their own care and regulatory policies that encourage access to a wide array of safe and effective non-prescription medicines. The former relies on individual empowerment gained through improved health literacy, credible and consistent sources of information about self-care, and aligned healthcare providers. The latter can be achieved through appropriate regulation of self-care products, including global mutual recognition among worldwide regulators, as well as increased reclassification of products from prescription to non-prescription status.

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GSCF is dedicated to a world where self-care provides individuals, families, and communities with the ability to manage their health and prevent diseases with or without the support of a health-care provider. Successful self-care provides individuals with greater choice of healthcare options and more accessible entries to care—e.g., through pharmacies; greater value for care when treating ailments and chronic conditions; and can lead to long-term better health outcomes. It also can decrease the burden on healthcare systems and professional medical personnel; increase freedom for innovation in healthcare; and make progress toward universal health coverage.

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