DELIVERING INFORMATION TO CONSUMERS THROUGH E-LABELLING

GLOBAL SELF-CARE FEDERATION

INTRODUCTION

The non-prescriptions medicines (NPM) industry is committed to improving health outcomes by providing information on product safety and improving access, and literacy amongst consumers. It is important that consumers are provided with medicinal product information that is reliable, understandable and in an easy-to-access format. Medicine packaging contains all the relevant information to enable consumers to use medicines in a responsible manner. Product Information (PI) is typically provided to consumers electronically or through paper leaflets available within packaging of the NPM itself. The aim of NPM PI, along with the outer pack, is to help consumers make an informed purchase decision when directly accessible (i.e. over the counter) and ensure that NPMs are used in an effective and responsible manner.

An e-label or e-product information (ePI) generally refers to information about a medicinal product provided by the product owner in compliance with local laws and regulations stored on a digital platform and intended to be delivered to consumers and healthcare providers through electronic devices.

ePIs may be accessed via interactive technology integrated into the packaging. Content provided by ePIs is typically created only for purposes of delivering information about the designated product.

Information stored on trusted machine-readable digital platforms is accessible 24/7 and can help to provide adequate and useful product information. These platforms can be hosted by authorities, market authorisation holders and 3rd party independent operators (e.g., in Sweden and Australia). Digital tools (e.g., QR codes) can help to deliver this information efficiently by providing individuals with access to information in a customised, enriched (e.g. with videos or other media), navigable and easy-to-understand format, simultaneously increasing consumer engagement and awareness of the product attributes which ultimately results in a responsible use of NPMs.

This need was also recognised by the regulators who expressed willingness to promote ePIs going forward. At the last International Conference of Drug Regulatory Authorities hosted by the World Health Organization, it was agreed that e-labelling as a tool should be promoted as a new normal [1]. Moreover, the European Commission highlighted in its 2017 report that current product information could be improved to better meet the needs of patients [2]. The report also highlighted that electronic format would bring new opportunities and the existence of potential benefits which can be achieved through developing key principles on how electronic formats can be used to provide information to individual EU citizens., The International Pharmaceutical Regulators Programme (IPRP) is currently developing an article on the importance of e-labelling and its future potential [3].

In terms of current global regulatory practices, ePI regulations are developing at different rates across the world. Currently, National Regulatory Authorities (NRAs) are discussing two regulatory pathways:

1 Regulations **do not require separate paper leaflets and sponsors can select how to provide individuals with the required PI** e.g., Australia, New Zealand, United States, and India. Under this approach, required labelling information is placed on the outer carton, to guide consumers in making informed purchase decisions and to provide information on responsible use of the product. The product information can be made available directly through ePI, unlocking all benefits of hosting information relevant to consumers digitally. This ensures that information available to consumers is always up-to-date and reduces the likelihood of confusion arising from availability of two sources of information (ePI and paper leaflets).

2 Regulations **do require paper leaflets** but a dual system with ePI as a supplement to paper leaflets could be considered e.g., EU, Canada, and Brazil. This hybrid approach may provide better reassurance on consumers' accessibility to product information. However, it may also lead to confusion, as ePI can be easily updated with the most up-to-date information, while paper leaflets within the packs are current when the medicine is supplied and cannot be updated once placed in a packaging.

GSCF believes that the use of the dual system (ePI and paper copy) for NPMs is an interim step towards an aspirational end-state where consumers will have access to product information through digital platforms. The steps in the journey to this goal should be achieved with agreement among all stakeholders on how to realise the many benefits of ePI while mitigating concerns about consumers' access to information. In countries that have an opportunity to leapfrog to digitalisation, ePIs made available by a trusted source (sponsors or NRAs) are an excellent approach to provide instant access to correct and up-to-date product information empowering consumers to use NPMs responsibly.

BENEFITS FOR CONSUMERS AND HEALTH SYSTEMS

The use of ePIs produces many benefits for consumers and health systems alike.

The production of a paper leaflet which currently accompanies finished products is time-intensive due to the gap between manufacturing runs, regulatory approval for updates to information, and distribution. The use of ePI, on the other hand, would allow consumers to have immediate access to the most recent regulator-approved product information.

ePI is also a great way to provide consumers with information in various forms, depending on demographics, in order to improve consumer engagement and responsible use. Some examples include:

Accessibility to consumers with diverse abilities: special consumer groups such as the elderly, visually impaired or with low literacy will benefit from solutions such as large-sized font, high screen contrast and audible formats (incl. audio-supported reading technology) of product information

Enhanced navigation tools such as a "search" function, hyperlinked table of contents, dictionary/glossary

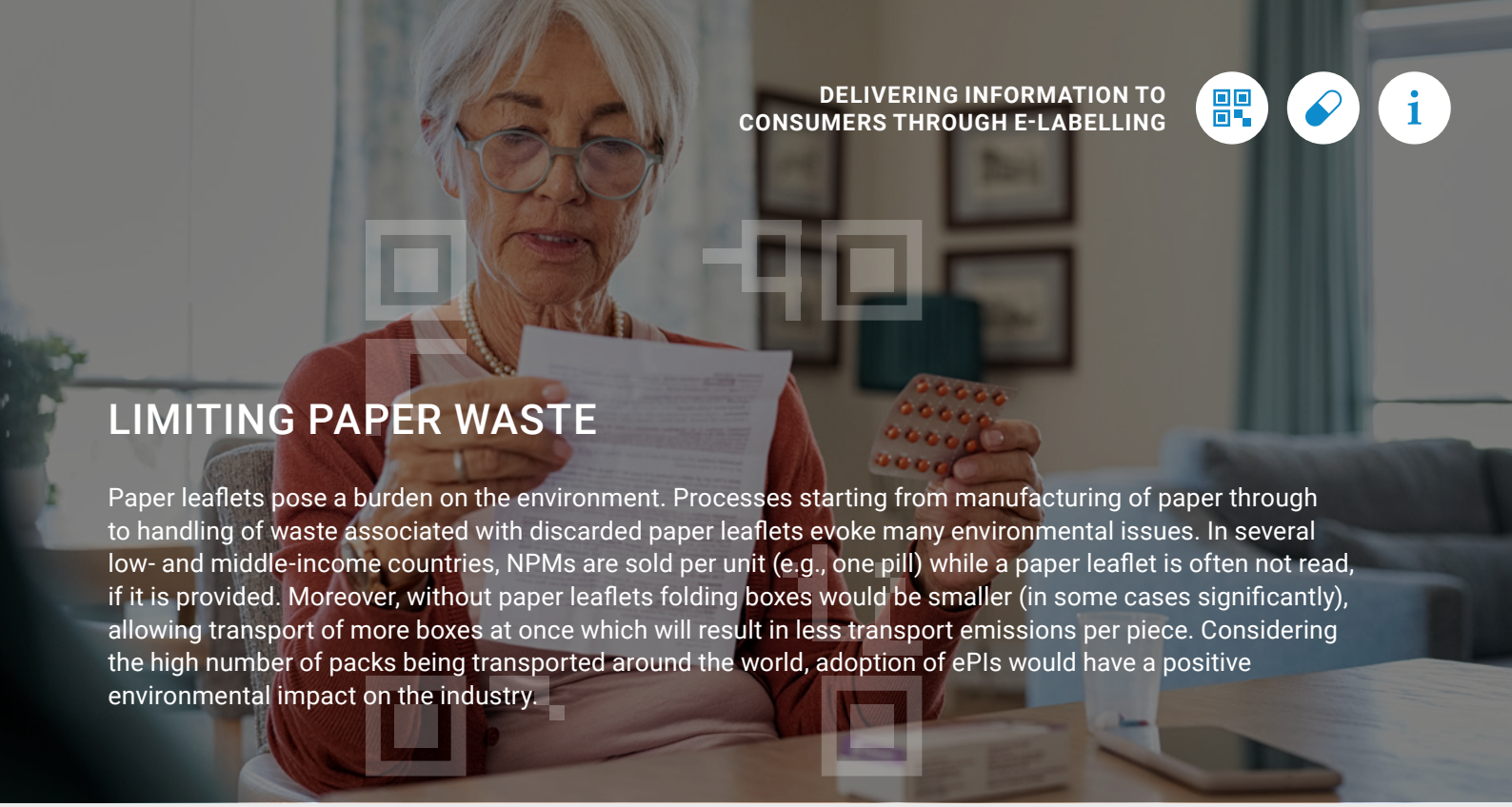
Interactive links for visual aids and instructional videos

Multi-language leaflets available for consumers (multi-language paper leaflets are lengthy, complex, and structurally challenging)

Support **consumer self-administration** through digital content (e.g., video and automatic language translation)

Another benefit to consumers can be brought through **personalized "push" alerts** (e.g. via digital apps in addition to ePIs) sent to individuals regarding taking a correct dosage of medicine at the appropriate time, expiry dates and refill reminders.

Potentially, information (e.g., ADRs / feedback on adherence to ePI) can also be 'pulled' from the consumer (which currently could be done with text messages). Therefore, **data interoperability** must be taken into consideration throughout the development process, starting from the ePI design phase. Design principles should also be harmonised in accordance with international standards. In the context of data privacy, ePI itself does not collect any personal data. However, when accessing ePI through a mobile application or a website, personal data may be collected and processed solely for the purpose of managing the implementation and use of ePI on various devices. In such cases, personal data is processed in accordance with applicable local or regional data protection legislation. Moreover, personalised "push" alert functionality is only implemented after obtaining prior consent from consumers.



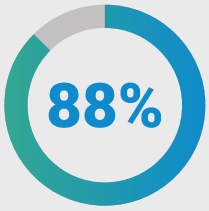
LIMITING PAPER WASTE

Paper leaflets pose a burden on the environment. Processes starting from manufacturing of paper through to handling of waste associated with discarded paper leaflets evoke many environmental issues. In several low- and middle-income countries, NPMs are sold per unit (e.g., one pill) while a paper leaflet is often not read, if it is provided. Moreover, without paper leaflets folding boxes would be smaller (in some cases significantly), allowing transport of more boxes at once which will result in less transport emissions per piece. Considering the high number of packs being transported around the world, adoption of ePIs would have a positive environmental impact on the industry.

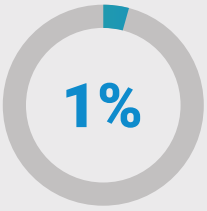
Data received in 2019 from the Brazilian National Association (Acessa - Associação Brasileira da Indústria de Produtos para o Autocuidado em Saúde) shows that 88% of the consumers purchase an NPM at least once a month, while only 1% asks a pharmacist for a paper leaflet when purchasing a blister pack. Simultaneously, Data from IQVIA demonstrates that for the 10 most sold NPMs in primary packaging (MAT 12/2018) in Brazil, more than 1 billion package paper leaflets are annually sent to pharmacies in line with the current regulations [4,5]. Considering that the average weight of a paper leaflet is equivalent to 0.5g, this is approximately 660 tons of paper per year (or about 10,000 trees per year). The number is even higher when the total number of paper leaflets available in primary packaging (including generic drugs) is considered.

Moreover, in some regions, packs are destroyed to implement labelling changes within a legally prescribed timeline, adding to the waste. At times, the actual packaging configuration may need to be enlarged to accommodate increased size of paper leaflets. Implementation of ePI would contribute to alleviating the amount of waste produced by the industry and would further the efforts to reduce its overall environmental impact.

During the COVID-19 pandemic, eCommerce served as an excellent avenue for consumers to self-medicate to treat minor ailments and self-treatable conditions. Non-prescription medications were one of the highest categories of products purchased online during the pandemic and this trend is further expected to increase by 44% post-pandemic as consumers begin to think digital-first worldwide [6,7,8]. Linking ePIs to eCommerce or e-pharmacy ensures that consumers can self-select the right NPM after reading NRA-approved information on the ePI. It would also enable consumers to easily find information on how to use the medicine responsibly.



of consumers purchase an NPM at least once a month



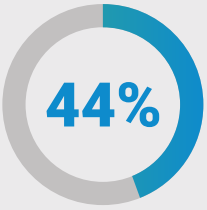
of consumers ask for a paper leaflet when purchasing a blister pack

1 billion

leaflets sent to pharmacies annually*

660 tons

avarage weight of paper leaflet per year



of consumers began to think digital-first after the pandemic

Data received in 2019 from the Brazilian National Association (Acessa - Associação Brasileira da Indústria de Produtos para o Autocuidado em Saúde)

*package paper leaflets annually sent to pharmacies for the 10 most sold NPMs in primary packaging in Brazil

KEY ELEMENTS FOR TRANSITION TO EPIS

FLEXIBLE APPROACH TO PRODUCT INFORMATION MANAGEMENT

The main objective of NPM product information is to ensure that consumers can appropriately self-select their products at the point of purchase (i.e., on shelf or eCommerce) and use them in a responsible manner. The full product information can be hosted on an ePI instead of being made available on the pack (or secondary packaging) or on a paper leaflet. Arguably, having access to ePI whilst scanning shelves would simply consumers' access to information when compared to the traditional method of looking to open packs and reading through lengthy leaflets. In order to fulfil its purpose, a mobile technology feature placed on packs should be clearly visible and must be accompanied by a clear guidance for the consumer on the use of machine-readable digital format. For instance, the EU guideline recommends providing the following information: "Detailed and updated information on this product is available by scanning [the QR code] [other two-dimensional (2D) bar code] [Near-field Communication (NFC)] included in the <PL> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website >". [9, 10]

Lastly, to avoid potential confusion and proactively manage potential discrepancies in information between ePI and paper leaflets, paper leaflets should include a clear recommendation for consumers to refer to the online version for the most up-to-date information. For instance, the EU guideline [9, 10] proposes to include the following sentence to inform users about the potential discrepancies which may be found in PI provided via mobile technology: 'Latest approved information on this product is available on the following URL ' at the end of the package leaflet or an additional line of text could be added to the paper leaflet to mention that the most updated version of the leaflet is available digitally through QR code available on the pack [11, 12].

ESSENTIAL SAFETY INFORMATION

To aid the transition to ePI, essential safety information should be available directly on the pack, while access to the complete safety and other required information could be made available through a digital solution (e.g., accessed via QR code or website URL). For instance, a study conducted in Sweden demonstrated that although most patients prefer to have PIs included in the package, they are also interested in and ready to use electronic resources. Like in all cases of digital transformation, it is crucial that patient education takes place before, during and after the transition while an option to print out paper leaflets at pharmacies and other points of sales when needed remains accessible to them [11]. In this case, a clear definition of the type of information that should be made available on the pack as well as the type of information which should be accessible through ePI could be agreed through consultations with the concerned NRAs and, subsequently, potentially harmonised globally. This minimal labelling information at the time of purchase should provide a customer with guidance on:

- If the NPM is appropriate for consumer with indication (what is it used for) and contra-indication (when it should not be used)
- How to use the NPM
- The type of action an individual can take to avoid or minimise the occurrence of an adverse event

Minimal labelling information must include the most important information that should stand out and facilitate readability depending on the size of the pack and a general statement to seek the advice of the pharmacist. An example of on-pack information can be seen in the Therapeutic Goods Australia's guidance on labelling and packaging for NPMs could also serve as a basis for on-pack information [13].

OPEN DIALOGUE BETWEEN NRAS, THE INDUSTRY, AND KEY STAKEHOLDERS

GSCF believes that an early dialogue and a strong collaboration between NRAs, the industry, and its key stakeholders such as patients, consumers, pharmacists, and healthcare professionals is crucial to establishing a harmonised patient and consumer-centric system.

This approach will ensure that all contributions from interested stakeholders and consumer groups are considered during the transition/implementation process.

Stakeholder engagement will provide insights into the way consumers will comprehend and interact with ePIs in real life. For instance, in November 2018, European Medicines Agency, Heads of Medicines Agencies and the European Commission held a joint workshop with all stakeholders to agree on common principles for the use of an electronic summary of product characteristics (SmPC) and package leaflet formats in the European Union (EU). They have also created a draft proposal to be submitted for public consultation before finalising their key principles document [9].

IMPLEMENTATION STEPS

An approach comprising the following steps can ensure a smooth transition to ePI under the leadership of the NRA, with timelines and milestones developed in consultation with the industry and stakeholders:

1

RE-DESIGN

of information to be consumer-friendly, succinct, legible, engaging and navigable in a user-friendly structured digital format where the format of paper leaflets is revisited

2

IDENTIFICATION

of already existing infrastructure or platforms as repositories of ePI

3

INCLUSION

of machine-readable digital format on the packaging to ensure consumers know where to find ePIs and can view them on digital devices (such as smartphones, laptops, and tablets) in an optimised manner. For example, Brazil allows the use of ePI (in multiple media formats) which can be accessed through a QR code printed on the pack, while maintaining mandatory paper leaflets [14]. As a part of the transition, paper leaflets can also be added to the pack with a note that the consumer should consult an electronic version for the most up-to-date information.

4

ESTABLISHMENT

of an implementation plan with realistic timelines on roll-out (considering the significant volume of marketed products) and subsequently, removal of the requirement for paper leaflets once the repository is fully functional and consumers are duly informed and aware of availability and functioning of ePI

5

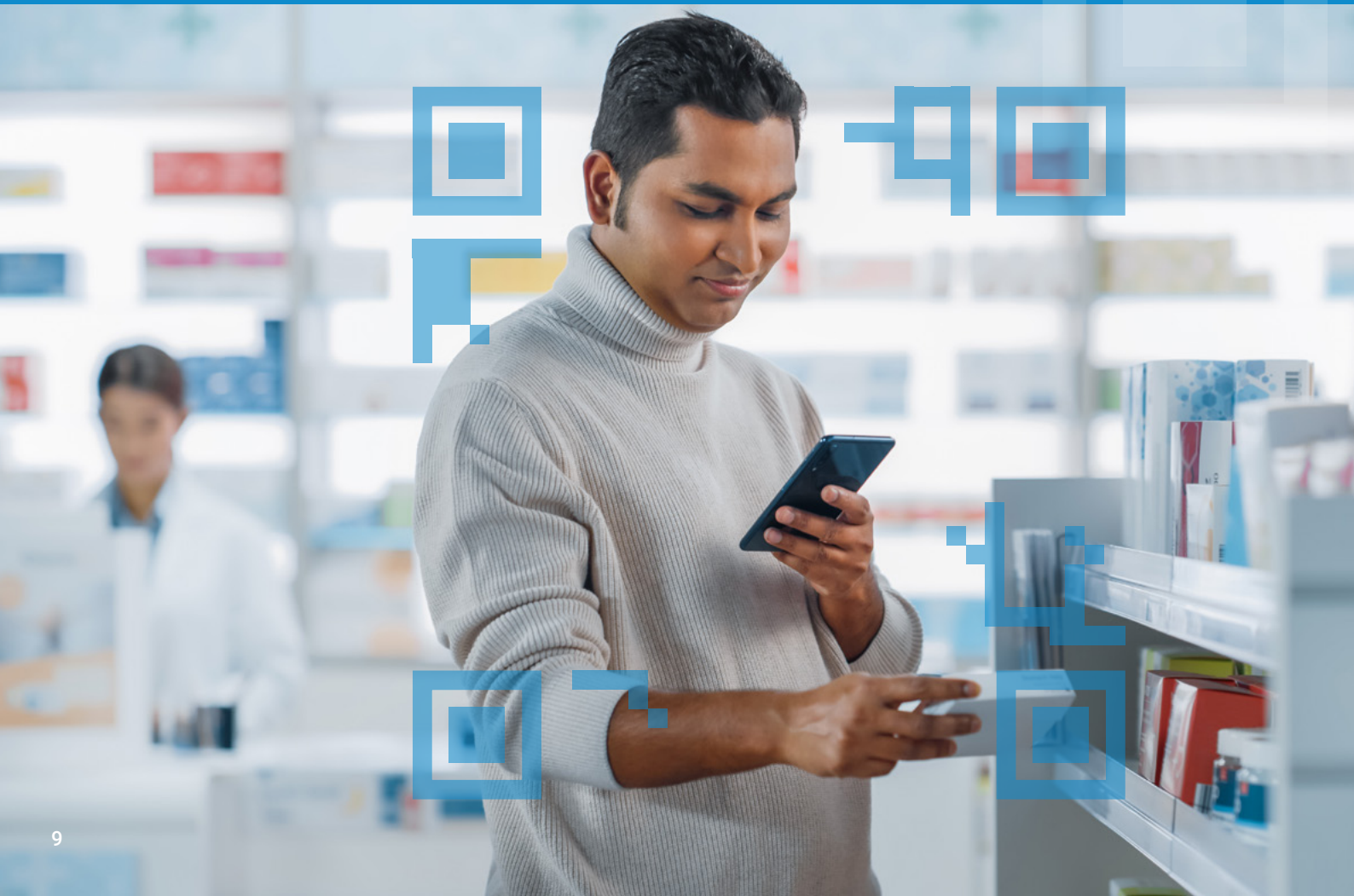
THE RESULT

of the transition would be an updated repository where information is stored in a structured manner, enabling searches, re-use, and interoperability with other digital healthcare platforms. The electronic product information would be implemented using an internationally recognised data exchange standard such as HL7 FHIR [15].

CONCLUSION

It is important that consumers are provided with up-to-date trusted information on their NPM to ensure that they can understand and use the NPM appropriately. The COVID-19 pandemic has further accelerated the shift towards a digital world, creating an opportunity for the wide use of ePI, particularly in low- and middle-income countries where risk communication was done using digital tools. Given its benefits, the NPMs industry considers ePI an essential tool in empowering consumers to address their healthcare needs.

GSCF believes that while the transition to ePI is an end goal, a dual system (paper and ePI) is an interim step. While designing future systems, it is essential to ensure flexibility and provide guidance to consumers on where to find the correct information online. Lastly, successful implementation is dependent on a collaboration between NRAs, the industry and stakeholders as well as developing a common understanding of the implementation plan and the roadmap.



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"It is vital for consumers to have reliable sources of information about medicines. E-Labels will widen access to such information, including for people with impaired vision. We welcome this position paper as a first-step to establishing e-labels so that they may be used in addition to advice from pharmacists that empowers self-care and enhances responsible use of medicines. We also welcome the access to regulator approved content."

DR CATHERINE DUGGAN

CEO, International Pharmaceutical Federation

"In a post-covid world, empowering individuals to manage their health brings great benefit to individuals, society and health-care systems. E-labels are a natural and strong tool to address the gap in accessing reliable information on responsible use of the non-prescription medication and it will come to hold a unique place in the digital society. While embarking on this digital journey, it is important to ensure a strong collaboration with patient to ensure needs of all patient groups are considered."

KAWALDIP SEHMI

CEO, International Alliance of Patients' Organizations

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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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