SPOTLIGHT: PROGRESS IN THE ADOPTION OF E-LABELLING FOR NON-PRESCRIPTION MEDICINES

GLOBAL SELF-CARE FEDERATION

INTRODUCTION

Electronic labelling, (e-labelling), is the dissemination of product information (PI) through digital formats hosted on publicly accessible websites and accessed via technological means, such as 2D barcodes or QR codes. This technology is incorporated on either the primary or secondary packaging of a medicinal product and in addition to the approved product information; it may include educational content in various formats such as video, images and or illustrations.

E-labelling has been shown to offer various advantages to diverse consumers, from ensuring information access to groups such as the elderly and those with specific accessibility requirements, to allowing for the provision of information in multiple languages.[1] For the consumer health sector, e-labelling promotes the appropriate use of non-prescription medicines (NPM) by empowering individuals to self-select and self-administer NPM even in the absence of a healthcare professional (HCP) which is often the case. To add to this, the concept aligns with environmental sustainability goals by limiting the waste that is generated from printed paper leaflets. This is particularly important given the fact that, as of 2022, over-the-counter (OTC) market volumes stood at more than 60 billion units (data provided by IQVIA).

In this context, adoption of e-labelling represents a step forward in creating a more accessible, sustainable, and efficient future for consumer healthcare stakeholders as detailed in the GSCF position paper[1]. This spotlight paper complements GSCF's position paper on delivering information to consumers through e-labelling by providing case studies related to the adoption of e-labelling globally, summarizing the case for e-labelling adoption for NPM based on evidence, and providing an overview of important factors that are specific to self-selection and appropriate use such as consumer centricity.

IMPORTANCE OF E-LABELLING FOR NON-PRESCRIPTION MEDICINES

Non-prescription medicines (NPM) have advantages that support implementation of e-labelling. Some of these include the fact that NPM have well-established safety profiles and a long track record of patient use, and they are selected and used based on the quality of information provided, frequently without the support of a HCP. However, despite these differences and specific advantages of this specific legal classification, NPMs are often excluded from e-labelling pilots, with hospital-only or prescription medicines being the focus of trial and adoption, often due to the distribution setting of these medicines being considered as an additional risk minimisation measure.

There is a need to broaden the scope of e-labelling pilots to include NPMs. Recommendations from a State of the Nation report on e-labelling in the United Kingdom[2], identify the need to co-design digital solutions with consumers / patients by running e-labelling pilots in real-life settings that includes the community. This way, the pilots reflect the diverse and evolving needs of consumers and patients. In addition, pilots involving NPMs can also add value by collecting more person-centric data, as in some hospital or prescription medicines scenarios, individuals may not always receive the labelling for the product anyway (in either the paper or electronic format).

Some of the advantages that stand out for NPM include:

1 The purchase and use of NPM frequently occurs in absence of support by HCP. The practice of self-care practice has been shown to translate into global savings of 40.8 billion productive days per year and 1.8 billion hours & 10.9 billion hours in physician and individual time savings respectively. **By 2030, this will translate into cost containment of approximately $178.8 billion per annum, as the strain on healthcare systems increases globally with decrease in the number of HCPs.**[3] With increased digitalisation, especially post the COVID-19 pandemic, consumers have become more accepting of and familiar with digital formats such as QR codes[4] and accessing patient information leaflets online is a step forward in empowering individuals to make informed decisions and take charge of their health. This is particularly important in the self-care framework and reinforces the self-selection objective.

2 E-labelling aids to improve the resilience of **pharmaceutical supply chains and facilitates timely access to NPM.** Pack sharing across smaller markets is required where countries may have low demand for a product and cannot meet minimum order requirements for supply to be viable to their market. The ability to digitalise approved country-specific labelling (approved based on national requirements) facilitates sharing of packs across countries. E-labelling is particularly relevant given the complexity of updating labelling information where the approval timings in NRAs differ. **In Guatemala, implementation of e-labelling for small NPM packs has been shown to be viable and the country is featured as one of the case studies.**

3 E-labelling facilitates the **dissemination of the most up-to-date information** particularly to the elderly **and to individuals with visual or other special needs.** This is particularly important for NPMs, where an HCP is not always present to assist the individual in understanding their health information. E-labelling eliminates printing limitations, allowing flexibility in accessibility features like read-aloud function, adjustable font size, line spacing as well as visual aids (videos and graphics) so that consumers may better grasp the information while making self-selection and self-medication decisions. In addition to this, users can magnify content on their screens, and can more easily search the text; features that are much simpler and more helpful compared to paper leaflets. This information would be accessible prior to the purchase of the medicine due to the code being on the outer pack of the medicine, which would help to ensure better decision making during the self-selection process.

E-LABELLING IMPLEMENTATION OVERVIEW: A CASE OF 6 COUNTRIES

SOUTH AFRICA AND SAUDI ARABIA

White paper and position papers, developed by trade associations for NRAs, have been shown to drive e-labelling advocacy and implementation of pilots (that include non-prescription medicines).

INDIA

E-labelling is acceptable for established and locally manufactured products.

GUATEMALA

Implemented e-labelling for small pack size (e.g. single/unit dose) non-prescription medicines.

BRAZIL

New labelling framework published in 2022 encourages companies to place digital codes i.e. QR codes, on package inserts.

AUSTRALIA

Paper leaflets are not required if all mandatory information is included on the product packaging.

A detailed overview of the progress of e-labelling for each of the 6 countries can be accessed in the accompanying individual country one pagers.

	Country	AUSTRALIA	BRAZIL	INDIA
Country Summary	Population	25.69 million	203.1 million	1.41 billion
	No of internet users	23.93 million	162.5 million	692 million
	Internet penetration rate (%)	89.60%	80%	48.7%
E-labelling Infrastructure	ePIL hosting platform	Both Health Authority (HA) & Marketing Authorisation Holder (MAH) websites. PIL may also be hosted on Doctors' prescribing software and Pharmacists' dispensing software platforms.	Both Health Authority & Marketing Authorisation holder websites.	Market Authorisation holder website.
	ePIL format (technology means used)	QR codes and website addresses are acceptable.	QR Code	QR code and website information on pack.
	Provision of label information (format)	The Australian Therapeutic Goods Administration (TGA) provides a mandatory template.	Under evaluation. • ANVISA (Brazilian Health Regulatory Agency) assesses EU electronic standard (premature discussion). • Formats being explored include: unstructured PDF, semi-structured HTML/XML and other formats adapted for electronic use.	Current regulations does not provide any provision/ format specific for E-labelling.
Regulatory Framework	E-labelling provision	Not mandatory to be done via an on-pack QR code. Digital format can link to promotional content as well. However, the ePIL must not contain promotional content. Promotional material must be clearly distingushable from the ePIL material.	• Mandatory submission of ePIL to HA. • Companies have the option to make ePILs available on their websites, after submission to the HA.	Not mandatory.
	Guidelines	The ePIL template and guidelines for Consumer Medicines Information (CMI) for non-prescription medicines can be found here: tga.gov.au	• RDC 47/09 published in 2009. • Law No. 14,338/2022 that prompted a review of RDC 47/09.	The format w.r.t. content is specified in 3rd schedule (Table 8) of New Drugs and Clinical Trial Rules- 2019 which is only applicable to new drugs.
	Products excluded/ included in e-labelling provisions	Medicines that must have a PIL (higher risk OTC pharmacy medicines and prescription medicines) may provide this electronically if they wish. However not all OTC medicines require a PIL.	QR Code approved for all products.	New Drugs: the PIL has to be included in the dossier submission for approval and uploaded online.
	Approval & update process for ePILs	The TGA and the MAH are responsible for updating their respective website content (keeping the ePIL and paper leaflet up to date is part of the MAH's pharmacovigilance obligations).	No specific guidelines, update in a timely manner once approved.	Both the company and marketing authorization holder are responsible for ensuring up-to-date product information (both paper & ePIL).

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	Country	AUSTRALIA	BRAZIL	INDIA
E-labelling	**Format**	Dual system (paper & digital). ePIL is accepted, if all the required information (mandatory directions, warnings and cautionary statements) is provided on the pack label.	Dual system since 2009.	Dual system: Paper leaflet required for new products. Fully electronic for locally manufactured old drugs.
	Implementation roadmap	The Therapeutic Goods Regulations 1989 do not specify how the Product Information (PI) and Consumer Medicine Information (CMI) should be distributed. **2019:** the Australian Government established a TGA-facilitated stakeholder working group consisting of industry, academics, healthcare professionals, communications experts and consumer groups to review previous research and user testing of CMI undertaken by the University of Sydney and the Electronic Distribution Working Group (EDWG), an independent committee that promotes and facilitates the electronic distribution of CMI to health professionals and their patients. The work done by this group resulted in a revised format for CMI, featuring new separate templates for prescription and non-prescription medicines, which have improved readability, reduced complexity, and are more suitable for reading on electronic devices by allowing use of hyperlinks and digital functionality. The new templates were implemented in **January 2021** and are now mandatory, with all registered medicines required to transition to the new format by **30 December 2025**.	**2009:** RDAC 47/2009. • Regulation that mandated companies to submit a digital version of the PIL in PDF to be stored in the HA electronic repository; in a file format that allows for conversion to audio and source magnification. **2019:** HA had discussions on the expansion of access to the digital package leaflet with the revision of the medicine labelling standard. **2022:** Law No. 14,338/2022 prompted HA to review RDC 47/2009. • New labelling framework published in 2022 allowing companies to place digital codes i.e. QR codes on packaging. • HA has opened a regulatory process to review the regulatory framework of package inserts, which will include: Regulatory Impact Analysis and Public Consultation. Currently, the HA is working on the standardization of digital leaflets.	OTC regulations are under development. Draft regulations did not have any mention of using e-labelling provisions, but industry provided comments to include this provision instead of paper leaflets.
	Stakeholders	Advocacy: industry, consumers, health professional and government representatives. Implementation: Health Authority.	Health Authorities, Industry/ trade association, consumers (surveys done).	
	Opportunities	**Unique opportunities:** The removal of paper leaflets when all mandatory information is included on the label.	**Unique opportunities:** • Some low-risk Prescription-free medicines (MIPs) are exempted from paper PILs by the HA if the mandatory information is listed on the product packaging. • MIPs sold directly in primary packaging have paper PILs available in pharmacies if the consumer requests and a survey from Brazilian Institute of Public Opinion and Statistics showed only 1% of the population asks for the PIL. **Challenges:** Lack of 100% internet access is a barrier to full transition.	**Opportunities:** As per current regulations, paper leaflet is only mandatory for new drugs. Hence, for all other products, paper leaflet can be transformed to e-leaflet.
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	Country	GUATEMALA	SAUDI ARABIA	SOUTH AFRICA
Country Summary	**Population**	17.1 million	36.6 million	60.14 million
	No of internet users	8.7 million	36.3 million	43.48 million
	Internet penetration rate (%)	65%	99%	72%
E-labelling Infrastructure	**ePIL hosting platform**	Marketing Authorisation holder website.	Health Authority website.	Health Authority website.
	ePIL format (technology means used)	QR Code	QR Code	QR code
	Provision of label information (format)	HTML	Data is uploaded on the NashraTech platform: nashratech.com	PDF
Regulatory Framework	**E-labelling provision**	Not mandatory.	Not mandatory.	Not mandatory.
	Guidelines		The GCC Guidelines for Variation Requirements.	No specific guidelines. These are combined with labelling guidelines and regulations.
	Products excluded/ included in e-labelling provisions	Only approved for small pack size OTC medicines.	For all centrally registered medicines.	None.
	Approval & update process for ePILs	Proposed labelling for e-labelling is assessed by the health authority for approval, which takes 5-6 months. The Marketing Authorization Holder is responsible for updating the website.	The introduction of ePILs is regarded as a variation.	The introduction of ePILs is regarded as a variation. The industry is responsible for updating the ePILs.
E-labelling	**Format**	• Current format: Dual system (complementary to paper PILs). • ePILs not accepted as a replacement for paper PILs.	Dual System pilot.	• Current format: Dual System with a plan to fully transition to e-labelling. • Professional Information (PI) does not need to be on the pack, can be electronic. • Patient Information leaflet (PIL) must be in/on the pack in two languages.
	Implementation roadmap	Small pack sizes with ePILs were first launched in **2021**. Industry sought to fix a challenge the regulator was facing. **Challenge:** Products in Central America and the Caribbean region of LATAM are dispensed and sold in unit doses to be affordable for low-income consumers. **Solution:** Adopt e-PILs to benefit low-income consumers to ensure access to full information for the small pack sizes.	**2021:** MENAP-SMI (Middle East, North Africa, Pakistan Self Medication Industry) developed an industry position paper on e-labelling. **2022:** the paper was submitted to Saudi Arabia authority followed by several meetings with Saudi Food & Drug Authority (SFDA) / Gulf Cooperation Council (GCC) authority. **May 2023:** SFDA / GCC issued guideline for Variation Requirements, to include "Addition of Electronic patient leaflet variation" Following the move by SFDA, other GCC countries are also adopting e-labelling.	**Currently in the planning phase** of a pilot to remove PILs in schedule 0 products. **Steps taken:** 1. Self-Care Association of South Africa **built an online directory** for all OTC PIs and PILs. The system can also generate a QR code for each product. 2. The association submitted a **white paper** to the regulator supporting the case for QR codes on packs. 3. Obtained buy-in from OTC companies to launch directory.

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	Country	GUATEMALA	SAUDI ARABIA	SOUTH AFRICA
E-labelling	Implementation roadmap	**Solution (continued):** • QR code proposal also enabled access to a common landing page that allows consumers to select which country they are in to receive access to the latest approved information. This simplifies logistics for industry to maintain this information for shared packs. **Steps taken:** • Developing proposals for the health authority on the benefit of e-labelling based on current challenges i.e. small pack sizes. • Discussions/meetings with the health authority on the challenge and proposed solutions. **Impact of COVID-19**: • Accelerated the adoption of e-labelling. • Influenced changes in consumer behaviour and fostered consumers' familiarity of using QR codes. • Adoption of QR codes increased across multiple sectors to support social distancing.	E.g. E-labelling guidelines were published by Oman in August 2023. Overview of the GCC NASHRATECH project timeline for GCC Countries - Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates. **Jun - Dec 2023:** Registration in the system and issuance of the QR code is mandatory for centrally registered pharmaceutical products. **Jan - Jun 2024:** Adding QR code on the outer pack is mandatory for centrally registered pharmaceutical products. **Apr - Jun 2024:** Evaluate the satisfaction level of the gulf society and the manufacturing companies and raise recommendations to implement the nashratech system on the peripherally registered pharmaceutical products and the transition to the next stage shall not take place without the approval of the peripheral drug regulatory authorities in the Member States. **Jul - Dec 2024:** Registration in the system and issuance of the QR code is mandatory for peripherally registered pharmaceutical products. **Jan - Jun 2025:** Adding QR code on the outer pack is mandatory for peripherally registered pharmaceutical products. **Jul - Sep 2025:** Evaluate the satisfaction level of the gulf society and the manufacturing companies and raise recommendations to remove the paper leaflet after the success of the trial period.	4. Promoted the directory: Developed a toolkit, launched a PR campaign and made the site zero-rated (no data costs incurred). 5. Obtained buy-in on the pilot: from both the regulator and the industry. 6. Piloting e-PILs Steps being taken: • Identify and obtain regulatory exclusions • White paper on ePIL pilot developed & and signed off by regulator. • Shortlist products to be piloted and establish a working committee. • Conduct consumer research on the number of people who use paper PILs. Compare results before and after the pilot. • Develop video content for pilot products (how to use the product).
	Stakeholders	E-labelling advocacy and E-labelling implementation: • Consumer Health Division at Bayer. • Health Authority in Guatemala.	E-labelling advocacy: • MENAP-SMI. E-labelling implementation: • Gulf Cooperation Council, SFDA.	E-labelling advocacy: • South African Health Products Regulatory Authority (SAHPRA), Pharmacy Council, The Health Professions Council of South Africa (HPCSA), industry. E-labelling implementation: • SAHPRA, industry.
	Opportunities	**Unique opportunities:** • Data supported by the telecommunication industry and local mobile phone company providers on mobile phone ownership, usage and access to the internet alleviated HA concerns on internet access. • QR code enables access to a common landing page that allows consumers to select which country they are in to receive access to the latest approved information.		**Unique opportunities:** • Zero rating the website addressed the issue of access in regard to data costs. • The self-care association of South Africa built trust by developing an online directory for the HA. Phase 2 of the directory will include RX products. **Challenges:** 12 languages are spoken in SouthAfrica.
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CONSUMER CENTRICITY

Consumer centricity in labelling involves developing product information that aligns with consumers' needs, preferences, and communication styles. This is particularly important for NPM because often, individuals independently select, use, and dispose off NPMs without HCPs oversight. Therefore, to derive the maximum benefits from labelling and instil confidence for practicing self-care (including self-treatment), it is crucial to ensure that the information provided is clear and easy to understand. Implementation of e-labelling fosters this by providing an excellent opportunity to review the content of the required product information and how it is provided.

The 4 A's principles below could serve as a basis for development of consumer-centric product information to ensure widest reach and understanding among consumers:

Availability

Consumers should be able to find product information readily, whether through packaging labels, accompanying leaflets, or online resources.

Acceptability

The product information should provide clear and comprehensive details that empower consumers to make informed decisions while avoiding overwhelming complexity.

Accessibility

Information that is accessible is written in a way that it may be used and understood by a wide range of users, including those from different backgrounds and with impairments.

Adaptability

Adaptable product information refers to content that can be adjusted or customized to meet the specific needs of different individuals, situation, or technology platforms.

The most critical product information should be available where it is most apparent to consumers, such as on the outer packaging of NPM. Some countries (e.g., Australia, Singapore, Malaysia) allow the omission of paper leaflets in NPM when all necessary product information can be provided directly conveyed on the outer packaging. Combining key product information on the outer packaging with access to full information in electronic format may be the way forward in moving away from paper leaflets and their limitations.

Another way to achieve consumer-centricity is through user testing studies that assess how effectively consumers are able to access, navigate, and comprehend an augmented electronic label versus a paper version.

As an example, the Australia Therapeutics Goods Administration (TGA), in 2019, conducted an evaluation on the usability of Consumer Medicine Information (CMI) documents on print and digital formats with consumers and produced an improved CMI template that is effective at communicating key medicine information and supports better understanding of medicines information.

Conducting studies to support label changes can be time-consuming and costly. The decision to conduct a study should be based on a benefit-risk analysis and GSCF recommends that factors such as population's familiarity with similar products, complexity of the product, the clarity of the labels, potential risk of misuse of non-prescription medicines are taken to account when generating evidence.

MINIMUM ESSENTIAL INFORMATION

Establishing clear guidelines outlining the minimum essential information on outer packs for NPM is a fundamental strategy for enhancing consumer-centricity and e-label uptake.

GSCF therefore recommends that the minimum essential information includes product and safety information on the outer pack labels of NPM primary packaging when secondary packaging is not available and vice versa. Multiple options approved by national regulatory authorities (NRA) for outer packaging should be provided to ensure companies can select the best option taking into account market and product specificities.

Minimum essential information on pack can help ensure consumers are informed about the essential product information and that full information can be accessed electronically.

CALL TO ACTION

It is evident that the potential for reshaping delivery of product information through e-labelling is significant and this has also been seen in other direct to consumer industries such as food, detergents and electronics.[5,6,7] To unlock this potential, all stakeholders must share a common understanding and collectively define concrete actions aiming at:

Fostering collaboration and engagement amongst key stakeholders, including NRAs, industry, consumers, and HCPs.

Develop a Global Regulatory Framework on e-labelling implementation, highlighting best practices.
Standardizing regulations and approaches to implementation will streamline the process and ensure consistency across regions.

Raise awareness about e-labelling through targeted educational programs.
These initiatives should focus on increasing understanding among both HCPs and consumers, highlighting the benefits, safety features, and accessibility of e-labelling. Consumers are increasingly embracing e-labelling and digitalization across many sectors.

Lessons learnt and improvement: Implement a "Try, test, Learn and improve" approach by conducting real-life pilots on e-labelling in partnership with NRAs.
Sharing the insights gained from these initiatives with stakeholders and other NRAs will help establish consumer-focused labelling guidelines.

In conclusion, **the progress made on e-labelling underscores the potential of e-labelling to serve as a catalyst for providing information to consumers in an easily comprehensible manner**. There is an immense need to transition to e-labelling, guide the shift towards a consumer-centric, digitally enhanced future for non-prescription medicines and the actions described above can pave the path for a healthcare system that harnesses e-labelling for the mutual benefit of consumers and the health systems at large.

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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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