



HEALTH · HYGIENE · HOME

# Enabling people to manage their health and wellbeing:

## Policy approaches to self-care



Written by

The  
Economist

INTELLIGENCE  
UNIT

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# About this report

**Enabling people to manage their health and wellbeing: Policy approaches to self-care** is a report written by The Economist Intelligence Unit and sponsored by RB, a UK consumer goods company. The report considers the key elements and drivers for self-care, and examines the political and regulatory response across three global markets: the US, Europe and BRICS (Brazil, Russia, India, China and South Africa).

The findings of this report are based on desk research and in-depth interviews with 12 experts drawn from healthcare professionals, patient groups, regulators, healthcare system groups, academics and industry bodies. Our thanks are due to the following for their time and insights (listed alphabetically):

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This report was written by Becca Lipman and edited by Elizabeth Sukkar of The Economist Intelligence Unit.

The findings and views expressed in this report are those of The Economist Intelligence Unit and do not necessarily reflect the views of the sponsor.

**October 2019**

## Foreword

Laxman Narasimhan, CEO of RB



Laxman Narasimhan  
CEO of RB

“Clearly, we need a new approach to healthcare that empowers people to look after their own health.”

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## Improving health literacy and education can have such an empowering effect on people's lives.

I'm new to RB, though not to the power of simple products like disinfectant to transform people's lives. Growing up in India, I was keenly aware that access to these products, and knowing how to use them, could literally mean the difference between life and death. So I am proud to be part of the RB family and its portfolio of consumer products for health and hygiene in the home, as well as the educational programmes that are an integral part of what RB is about.

Improving health literacy and education can have such an empowering effect on people's lives. And yet its importance is underplayed in healthcare policymaking today. This is one of the reasons for this report. We believe that enabling people to manage their health and wellbeing is key to solving the multiple healthcare crises across the industrialised and developing world, and to relieving pressure on overburdened healthcare systems. To achieve this, we need the commitment of all stakeholders towards initiatives that put the patient at the centre of treatment, an equal commitment to better education, and a greater emphasis on self-care.

RB has long been committed to health and hygiene education. For example, our hand washing campaign is now part of the school curriculum in nine Indian states – soon to be 14 – and is central to RB's new mother and baby outreach programme. In Pakistan, we have a programme aimed at preventing infant deaths from diarrhoea. This has reached 2.4 million children a year and more than 600,000 rural households since it launched in 2017. Over the past five years, RB's health and hygiene messaging has reached more than 765 million people. The goal is to reach one billion by 2025.

Our healthcare systems are rapidly becoming unsustainable. In emerging economies – from Brazil to China – governments still struggle to provide universal healthcare. Health literacy is poor, the primary care system patchy and hospitals overstretched. In OECD countries, health spending already stands at 15% of all government expenditure. As populations age and the incidence of chronic ailments rises – in rich and poor countries alike – demand for health services and pressure on budgets will only increase.

Doctors in the EU spend one-third of their time consulting on minor ailments, according to the Pharmaceutical Group of the European Union, that robs time and resources from more serious cases. Coughs, colds, headaches and backaches make up the bulk of clinical visits, which in many cases could easily be managed by people themselves if they knew how. In some countries where the primary healthcare system is underdeveloped, people are seeking treatment in hospitals, which is highly inefficient.

Clearly, we need a new approach to healthcare that empowers people to look after their own health, freeing resources for patients who really need medical care.

Let me be clear: self-care does not mean no care. It means giving patients a greater role in their healthcare, with appropriate guidance from the relevant professionals. Depending on the condition, that guidance may come from a family doctor or specialist, a nurse, pharmacist, patients' group, trusted healthcare website, call centre or product information and labels.

Consumer healthcare brands want to, and can, effectively play a role in alleviating our global healthcare crisis. Such products can often be the first line of defence against preventable diseases, helping people to manage the symptoms of short and long-term conditions. We provide innovative self-care solutions to help people live healthier lives, to prevent them from falling sick – and help them get well when they do.

We hope this report will help stimulate a conversation about how to put our healthcare systems on a more sustainable path – and the important role of self-care within it.

## Foreword

Zephania Jordan, chief safety, quality, regulatory and compliance officer at RB



**Zephania Jordan**  
chief safety, quality, regulatory and  
compliance officer at RB

“We hope this report will support policymakers to move towards formally including self-care in healthcare frameworks at national and international levels.”

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# 20%

**of NHS 111 callers are given self-care advice, potentially saving millions of medical visits a year.**

Three years ago, RB commissioned its first report on consumer health.<sup>1</sup> It focused on how non-prescription, or over-the-counter (OTC), medicines could play a more significant role in helping patients manage their wellbeing. It also discussed the challenges around different regulatory systems, finding that there was little agreement on what should constitute harmonisation because of political and cultural differences.

From the RB perspective, we would like to see regulatory harmonisation. Across the world, even across Europe, the same medicine can be classified as prescription-only or OTC, depending on local norms. Channels through which OTC products can be sold differ. There are pockets of harmonisation of regulatory standards but for the most part every country is different.

There is an economic cost to this regulatory disharmony, but there is an even bigger loss to patients and healthcare systems.

Studies show that when people are taught how to lead healthier lives, prevent or treat common ailments, or manage chronic conditions, their confidence improves. Studies also show they're more likely to stick to their treatment. Health outcomes improve and the burden on health services falls. That's why RB believes self-care should be a key pillar of sustainable healthcare systems.

Prevention is an important domain of self-care. For example, as a leading manufacturer of condoms, we have been at the forefront of safe-sex messaging for decades. Our campaigns reached 2.1 million young adults in 2018 alone. We recently partnered with the HIV charity (RED)<sup>2</sup> to fund a "Keeping Girls in School" programme in South Africa. Already, nearly 370,000 young women have been reached by the campaign, which aims to reduce new HIV infections and pregnancies by encouraging girls to stay in education.

Health and hygiene players like RB should be seen as natural partners for initiatives to promote healthier lives. After all, we know how to reach millions of people to raise awareness and influence behaviour change.

This new report looks at how self-care is perceived throughout the world and argues that if self-care were established as a core pillar of healthcare policies and national strategies, then better health outcomes would be achieved.

This is beginning to happen, albeit at different speeds in different countries. NHS 111 operators connect 1.5 million callers a month with local services in the UK and the reports show that about 20% are given self-care advice, potentially saving millions of medical visits a year. Japan has introduced a self-medication tax-deduction scheme with the aim of reducing reliance on prescription medication, thus freeing hospitals and clinics from patients with minor ailments.

Nevertheless, these initiatives are disjointed. Until self-care is established as a policy priority, we are unlikely to see the regulatory reforms and the incentives for further innovation and research to realise its benefits in delivering improved health outcomes – both directly, and by taking pressure off healthcare professionals so they can dedicate more time to patients in most need.

We hope this report will support policymakers to move towards formally including self-care in healthcare frameworks at national and international levels.

RB will continue its efforts to help drive evidence based reforms in self-care. Policy efforts, including the commissioning of this report, will be led by Flavio Kakimoto (VP regulatory, EURANZ, global policy & global eCommerce) and Grace Li (head of regulatory, global policy & eCommerce).

# Executive summary

Self-care entails actions that people take to promote or maintain their health and wellbeing. This encompasses an active role in the management of minor, self-limiting conditions as well as taking a greater role in any diagnosed medical conditions that involve partnership with healthcare professionals (HCPs).

In this sense, the human species has always practised self-care through daily choices and lifestyle decisions, long before doctors and health systems emerged. Old as the concept may be, self-care has become an increasingly important policy in recent years, where it needs to work alongside formal services to boost people's health and wellbeing.

The growing impetus to further engage populations in their own health practices is largely in response to the financial pressures on health systems. Although these have advanced considerably in their ability to treat and monitor patients, this has come at a great economic cost to governments and citizens. By encouraging populations to self-care, this will lower demand for formal health systems.

Yet the transition from professional care to more self-care is complex. Many cultural, systematic and safety barriers to patient involvement remain. And the role of policymakers and HCPs to safely empower populations to self-care is not always clear.

To address the challenges, this report will first examine the definition, components and drivers for self-care, and how self-care is already being adopted. Next, we will explore the challenges and benefits associated with self-care and the role of policymakers, HCPs, patient groups and industry organisations in promoting safe, accessible self-care. Finally, it will look at developed and developing markets – Europe, US and the BRICS (Brazil, Russia, India, China and South Africa) – to explore and compare today's political and regulatory approaches to self-care, and the impacts of those decisions.

## Key findings of the research include:

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### From a modern public health perspective, a self-caring population is a necessity.

It has become socially and economically unsustainable to maintain the traditional, ever-advancing delivery of care. Health spending already stands at around 15% of all government expenditure across OECD countries.<sup>3</sup> And global demographic shifts – namely ageing populations and rising chronic diseases among them – are driving greater demand for health services.<sup>4</sup> Reforming health services to advance self-care practices is therefore increasingly becoming a priority.

### People are eager to self-care.

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Many people lack confidence in maintaining their health and managing their condition, but are eager to do more. Studies show that patients who are educated about their condition and care, from common colds and sexual diseases to diabetes, may see better adherence to treatment plans. Those engaged with self-care also show optimal health outcomes and a higher quality of life, while putting less strain on the health system.



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## Health literacy is a critical enabler for self-care.

It empowers people and societies to transform health. Health literacy is needed to promote health equity and our research shows there is significant room for improvement and for greater research. For example, rural areas in China with low health literacy have higher instances of hypertension than their urban, relatively educated counterparts.<sup>5</sup> Low literacy rates can be lifted through life-long learning programmes that begin at school and continue through adulthood.

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## HCPs should be engaged in people's self-management practices.

Self-care does not mean no care, but it is not always clear where and when it is appropriate for HCPs to transfer care responsibilities to people. Interviewees suggest patients will be most successful when HCPs are trained to support them in self-care and can provide guidance as appropriate.

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## Self-care will increasingly be built into healthcare policies and play an integral role in healthcare systems.

More focus should be highlighted in policies on how self-care can improve health and wellbeing in concert with formal healthcare systems. Nonetheless, strong healthcare systems should empower self-carers. Countries can promote self-care by providing populations with effective, efficient and inclusive primary care services, quality healthcare information, and easy access to preventative care services and supplementary care. While some European countries like the UK have demonstrated the benefits of this approach, the BRICS countries show significant issues in this area, and consequently face overwhelming demand for emergency care services. In the long term, systems will benefit from less wasted resources across primary and secondary care services.

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## The ability to self-medicate, especially for self-limiting conditions, is an important component of self-care.

The availability of over-the-counter (OTC) medicines can lessen reliance on prescription medicines and could relieve the burden on healthcare systems (such as primary care) from patients seeking medication for minor ailments. Regulators must be content with the risk-benefit balance of a product to human health. Our research finds that they differ in their assessment of when it is safe to switch medicines from prescription-only to OTC. Nonetheless, it is evident that a range of OTC medicine has been expanding in most markets. Regulators will need to seek a balance in improving access to innovative and effective self-care technologies while maintaining consumer safety, quality and efficacy.

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## Medical devices, apps and e-pharmacies are shifting self-care dynamics.

Most regulatory bodies are embracing technological advances in healthcare, particularly those that can aid populations to better manage chronic diseases and help prevent future medical issues. Pills embedded with a sensor that remind patients to take their medicines, for example, have already been approved in the US.<sup>6</sup> Regulators are learning to focus their attention, as it is becoming impossible to oversee the flood of applications, devices and e-pharmacies entering the market. It would be helpful if healthcare systems provided information to people on trusted and safe digital tools and apps.

## CHAPTER 1

# Evolution of self-care



Population growth and demographic shifts have led to healthcare budgets being stretched, and there is a push for citizens to take greater responsibility for their own healthcare.



The cost and burden on healthcare systems falls when individuals can take action rather than engaging professional medical services.

Self-care does not mean the absence of healthcare professional partnerships or collaboration.



Studies draw correlations between low health literacy and both poor health outcomes and increased costs.



Access to medicines is an important part of self-care and essential for empowering patients to engage in their personal health.



There are many areas where digital technology will play a role and improve self-care's role in healthcare systems, such as monitoring blood pressure and adherence to health plans.

# Evolution of self-care



Self-care is what people do for themselves to establish and maintain health, and to prevent and deal with illness. It is a broad concept encompassing hygiene (general and personal), nutrition (type and quality of food eaten), lifestyle (sporting activities, leisure etc.), environmental factors (living conditions, social habits etc.), socioeconomic factors (income level, cultural beliefs etc.) and self-medication.

World Health Organisation  
(WHO)



It has already been verified that the joint responsibility of the patient influences the success or failure of the therapeutic measure. Self-care practices have developed from theories which are prescriptive, normative and of vertical extension. They are symbolised by actions that the health professionals would have wanted the patient to perform in their absence.

William Dib  
director-president, ANVISA

## What is self-care?

There are many official definitions of self-care. Fundamentally, it is the ability to maintain and improve one's health, prevent or limit diagnosed illnesses, and address self-treatable conditions. The ability to self-care is universal, regardless of socioeconomic or geographic status, and irrespective of the nature of the local healthcare system.

Critically, the cost and burden to individuals and society falls when individuals take action rather than engaging professional medical services.<sup>7,8</sup> Research also suggests that individuals empowered to participate in and choose aspects of their care have a higher quality of life, demonstrate better adherence to medications and make fewer hospital visits.<sup>9</sup> They may also adopt healthy behaviours in all stages of life.<sup>10</sup>

Advocates of self-care are keen to point out that it fits naturally within the concept of patient-centred care.<sup>11,12</sup> Both place emphasis on respecting and empowering the patient and improving their health literacy, and both evolve a traditionally provider-focused healthcare system towards one that gives patients a more active role in their treatment and care.<sup>13</sup>

Self-care does not mean no care.<sup>14,15,16</sup> Although self-care is fundamentally actionable by the individual without professional medical consultation, no stakeholder wants patients resorting to self-care because there was no available alternative. For self-care to succeed, there must be space to interact effectively with HCPs to ensure that patients' needs are expressed and addressed, as well as the availability of social support networks and patient groups.

Naoyuki Yasuda, director of the office of international regulatory affairs at the Japanese Ministry of Health, Labour and Welfare, agrees that self-care and professional care must complement one other: "While citizens may lead healthy lives that help prevent lifestyle-related diseases, it is also very important to actively provide screenings for each type of cancer, vaccinations, specific medical check-ups and health guidance, as well as aftercare and self-medication based on accurate diagnosis," he says. "The appropriate involvement of doctors is a necessary part of that cycle."

"Self-care needs to be integrated into the entire healthcare system. And the health professionals and the patients should know where the boundaries are to this," adds Kawaldip Sehmi, CEO of the International Alliance of Patients' Organisations.

"It has already been verified that the joint responsibility of the patient influences the success or failure of the therapeutic measure. Self-care practices have developed from theories which are prescriptive, normative and of vertical extension. They are symbolised by actions that the health professionals would have wanted the patient to perform in their absence." – William Dib, director-president, ANVISA

### Definitions at large

Researchers and policymakers use more than 100 different definitions of self-care to categorise behaviours and set parameters for research.<sup>17,18</sup> However, the most commonly cited come from the World Health Organisation, and particularly the 1998 definition:<sup>19,20</sup>

“Self-care is what people do for themselves to establish and maintain health, and to prevent and deal with illness. It is a broad concept encompassing hygiene (general and personal), nutrition (type and quality of food eaten), lifestyle (sporting activities, leisure etc.), environmental factors (living conditions, social habits etc.), socioeconomic factors (income level, cultural beliefs etc.) and self-medication.”<sup>21</sup>

According to the International Self-Care Forum UK, self-care can best be seen as a continuum. Pure self-care is at one end, intermittent self-care for minor illnesses and the management of long-term conditions is somewhere in the middle, while increasing reliance on healthcare systems as illness becomes more complex or demanding is at the other end (the continuum is represented in dimension 3 of the diagram below).<sup>22,23</sup>

Austen El-Osta, director of the Self Care Academic Research Unit (SCARU) at Imperial College London School of Public Health, says: “We are very careful here at SCARU not to add another definition to self-care. We’re keen to advance the notion that self-care is all encompassing, and it includes self-management, pure self-care and assisted care. All of these things are interconnected.”

## THE SELF-CARE MATRIX, PROVIDED BY THE INTERNATIONAL SELF-CARE FOUNDATION. THE RANGE OF SELF-CARE ACTIVITIES IS BROAD, BUT MUTUALLY ENHANCING.<sup>24</sup>

### Macro

System focused  
Policy & culture

## 4. Self-Care Environment

Wider determinants of health, fiscal policy, health policy, prevailing culture and the built environment

### Meso

Patient-centred  
Resource utilisation



## 3. Self-Care Context

Individual/social network focused  
Motivation, activation & change

## 2. Self-Care Behaviours

### Micro

Person-centred  
Individual capacities & capabilities

## 1. Self-Care Activities

Knowledge & Health Literacy	Mental Wellbeing, Self-awareness & Agency	Physical Activity	Healthy Eating	Risk Avoidance	Good Hygiene	Rational Use of Products & Services
1	2	3	4	5	6	7

7 pillars of self-care

# Evolution of self-care

# 30%

## of visits to physicians are unnecessary

According to the Pharmaceutical Group of the European Union (PGEU), an association representing more than 400,000 community pharmacists throughout Europe, 30% of visits to family physicians are unnecessary. Coughs, colds, headaches, sore throats and backaches make up the bulk of these clinical visits, which could be easily managed by patients themselves, according to the Proprietary Association of Great Britain (PAGB), a UK trade association for OTC medicine manufacturers.

### The need for more and better self-care

Modern healthcare services are economically unsustainable. Global average life expectancy is rising,<sup>25</sup> infant mortality is declining<sup>26</sup> and The Economist Intelligence Unit forecasts that global health spending will grow by 4.1% per year in 2017-21, up from 1.3% in 2012-16.

Dr Edward Kelley, director of the Service Delivery and Safety division at the World Health Organisation (WHO), says that on balance it's clear that healthcare systems across the globe should be moving towards self-care heavy models. In particular, more self-care is necessary to prevent and manage the rise of chronic diseases.

"If you look at the factors that influence health outcomes, only about 20% of it is the access to and quality of healthcare itself, the rest are around social, environmental and economic factors and health behaviours," he says.

If at-home factors such as healthy diets, exercise and tobacco use can be improved, then incidence of non-communicable diseases (NCDs) such as stroke, heart attack and cancers will drop.<sup>27</sup>

Unfortunately, patients are too often unaware of how to maintain healthy lifestyles, comply with medications, and do not feel comfortable or knowledgeable enough to identify, prevent or manage minor or self-treatable illness.<sup>28,29</sup> The result is a healthcare system overwhelmingly burdened by avoidable clinical and emergency visits.<sup>30,31,32,33,34,35</sup>

According to the Pharmaceutical Group of the European Union (PGEU), an association representing more than 400,000 community pharmacists throughout Europe, 30% of visits to family physicians are unnecessary.<sup>36</sup> Coughs, colds, headaches, sore throats and backaches make up the bulk of these clinical visits, which could be easily managed by patients themselves, according to the Proprietary Association of Great Britain (PAGB), a UK trade association for OTC medicine manufacturers.<sup>37</sup>

"If you don't believe self-care has any place in health systems, then you better visit an accident and emergency room on a Saturday night," says Mr Sehmi. "This is where you find diabetics that had too much alcohol and a host of other avoidable cases. And yet, the amount of time spent on this is distracting resources from genuinely critical cases, such as road accidents."

"The paradox is the better the health system, the worse self-care may be," thinks Dr David Webber, president of the International Self-Care Foundation. "Sick patients have to put themselves in the hands of the system and a degree of dependency can build up."

Looking forward, Dr Webber says we need to help people evolve from being passive patients into proactive participants in their own health. And we need to evolve healthcare systems from sickness systems into prevention systems.

"Almost no country would raise issues against the idea that people need to be more engaged in their care," says Dr Kelley. "Waves of chronic care patients are drowning health systems. And this is going to be one of the – if not the key – tools that they should be looking at to manage their health services in a more people-centred and in a more cost-effective way."

"But it is a very sensitive issue," Dr Kelley adds. Problems can arise when a country's policies raise warning flags that governments are stepping away from their responsibility in healthcare.

But if positioned correctly alongside formal services, self-care policy can empower patients, families and communities to be more engaged in their own care.

Although complex, self-care is an established arena for policy and services delivery, and there is still room for improvement in the take-up of self-care policies. A variety of legal and supportive frameworks exist,<sup>38</sup> from the WHO's People-Centered Health Care: A Policy Framework<sup>39</sup> to regional plans like Gloucestershire's Prevention and Self-Care Plan.<sup>40</sup>

Research in this space is also growing; so much so that the International Center for Self-Care Research in Rome is striving to connect isolated self-care researchers across the globe to better understand how and where self-care can be most effective.<sup>41</sup>

### Five drivers of self-care

Successful self-care is a culmination of many factors. Each population and each condition may benefit from different policies and initiatives, which proves a complicated web for stakeholders. This group can include HCPs, consumers and patients, patient bodies, policy or decision-makers, and industry players.

Cutting through the multitude of approaches, there are five supportive pillars that universally improve self-care: health literacy, healthcare professionals, healthcare systems, medication and technology. Each can be aided through policy and funding efforts.

## 01 Health literacy

Health literacy is the ability of a person to locate and evaluate relevant health information and apply it in ways that prevent illness and improve their health-related behaviours.<sup>42</sup>

Health literacy is a critical enabler for self-care, as it empowers people and societies to improve their health. People with low health literacy tend to abandon self-care and seek advice from a doctor earlier than necessary for self-limiting minor ailments.<sup>43</sup>

Patients with low health literacy may also struggle with the transfer of care responsibilities, which may lead to non-compliance with medication, missed appointments and lack of follow-through on tests or referrals.<sup>44</sup> All of these consequences can result in further health issues and costs.<sup>45,46</sup> In the US, for example, health illiteracy costs an estimated US\$100bn per year.<sup>47</sup>

On the other hand, evidence shows that health literate people demonstrate more confidence in decisions relating to healthy choices, self-diagnosis, self-treatment and the effective use of medicines and health technology.<sup>48</sup> Research also shows that patients with the autonomy to choose aspects of their self-care are linked with better adherence to treatment plans and healthier behaviours in all stages of life.<sup>49,50,51</sup>

Unfortunately, although health literacy is measured differently across studies, the consensus from available research finds that health literacy among populations is generally low, suggesting that too many people lack adequate skills to successfully manage their own care.<sup>52,53</sup>

For example, nearly half of European and American adults across respective national studies demonstrate inadequate health literacy skills.<sup>54,55</sup> Health literacy is also worryingly low across developing economies such as India and China.<sup>56,57</sup>

There are many ways of increasing health literacy. At a high level, national plain language initiatives help simplify formal communication for patients by making instructions and labelling shorter, simpler and more direct.<sup>58,59,60,61,62</sup> National strategies can also encourage medical professionals to undergo patient communication training programmes to improve patient comprehension during clinical visits.<sup>63</sup>

Post-recovery care is another prime area for greater health literacy intervention. For example, in order to expect better future outcomes after a heart attack, the patient must undergo intense coaching, rehabilitation programmes, health literacy improvement, and receive advice from dietitians and nutritionists.<sup>64</sup> Otherwise, they will soon be back at the hospital.

Mr Sehmi explains: "A heart attack or the asthmatic problem often happens due to lack of self-care in the first place. To then expect these people to go back and [undertake] self-care is not possible without some kind of intervention."

Health literacy is also proven effective when coupled with patient empowerment, whereby patients are given access to the tools to self-care in addition to the training.<sup>65</sup> For example, a growing body



If self-care does not go hand in hand with health education and health literacy provided by medical professionals, there is the potential for incorrect self-diagnoses and missed opportunities to take the right measures at the right time, which can have serious consequences. It's important for the various actors involved to understand this point.

**Naoyuki Yasuda**  
director of the office of international regulatory affairs,  
Japanese Ministry of Health, Labour and Welfare

of research around chronic disease management finds that patients taught to administer their own treatment show promising patient outcomes, improved quality of life and lower hospitalisation rates. This includes dialysis at treatment centres, IV antibiotics treatments at home and diabetes management.<sup>66,67,68</sup>

Interviewees are also quick to remind that health literacy is not a one-off effort. Rather it is lifelong learning, and therefore a continuous investment.

"Self-care doesn't come cheap. It doesn't mean no work," says Mr Sehmi. "Self-care needs investment in health literacy and digital health. You need hospitals well connected to all the community to educate. You must have schools' curriculums changed, and update the curriculum of medical students. All that is an investment, and it doesn't show results until much later."

"Quick fix solutions are futile," adds Austen El-Osta, director of the Self Care Academic Research Unit. "Changing behaviours once they've set in is hard – which is why we need to instil health-seeking and good self-care behaviours from a young age... We need to work with what we have and make sure there are interventions in place from school age and beyond where people are empowered to self-care."

Mr Yasuda says: "If self-care does not go hand in hand with health education and health literacy provided by medical professionals, there is the potential for incorrect self-diagnoses and missed opportunities to take the right measures at the right time, which can have serious consequences. It's important for the various actors involved to understand this point."



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# US\$3.3bn

potential savings

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Some calculations suggest potential healthcare system savings of US\$3.3bn if just 5% of American adults with one or more chronic conditions undergo self-management education programmes.



# Evolution of self-care

## 02 HCPs and patient groups

For self-care to be successful, there must be an enlightened healthcare workforce (e.g. doctors and pharmacists) with the right skills and competencies to support people undertaking self-care.<sup>69</sup>

“Doctors and pharmacists should be keen to support patients looking after themselves,” according to Ian Hudson, CEO of the Medicines & Healthcare products Regulatory Agency (MHRA) in the UK. “You also need appropriate guidance in terms of when it’s appropriate for people to look after themselves, and how doctors can help them do that.”

This does not always come easily. HCPs have traditionally been somewhat paternalistic and preferred that patients are professionally diagnosed and treated rather than risk a belated or missed diagnosis and poor self-treatment.<sup>70,71,72</sup> And indeed, medical professionals share concern around determining when it is appropriate for patients to take on care responsibility, and when there may be a great risk of improper medication use and other unintended damage to health.<sup>73,74</sup>

And HCPs are not usually trained to help patients transform into self-carers. “There’s a lack of time. There’s a lack of clear policy options. There are cultural considerations. Unsurprisingly, there can be resistance to moving on,” says Mr Webber.

According to interviewees, in general terms, self-care is hardly taught to medical students at the undergraduate level.<sup>75</sup> Nor are they sufficiently trained in how to interact with new digital apps and devices that increasingly enable patients to self-care.<sup>76</sup>

Scott Melville, president and CEO of the US Consumer Healthcare Products Association (CHPA), an American trade association representing manufacturers and distributors of OTC medicines and dietary supplements, agrees that doctors must learn to evolve: “Most consumers have access 24/7 to information technology. They can diagnose their condition much more quickly, and can self-select products much more so than they could ten years ago, and even four years ago. So this idea about a paternalistic healthcare system where you go to the doctor for everything, that’s not where we are today, and it’s not where we’re going in the future.”

Indeed, it is a new reality in which HCPs – and patients – must learn to operate. And utilised correctly, doctors, pharmacists and patient groups play a vital role in helping people to make more informed choices about self-care.<sup>77,78</sup>

Pharmacists, who already play a leading role in self-care, can usually be utilised more effectively.<sup>79</sup> Ilaria Passarani, secretary-general at the PGEU, explains that one of the main goals of a pharmacist is to ensure appropriate and safe self-care by providing information and advice to patients including around the use of non-prescription medicines.<sup>80</sup>

“The pharmacists check whether the medicine is suitable for the person and for possible interactions with other medicines and supplements. They explain how to use the medicine safely and appropriately,” Ms Passarani says.

Pharmacist consultations also provide an opportunity to advise on other issues like obesity, smoking and substance misuse, and direct them to the healthcare system if there is a need.

Unfortunately, pharmacists are generally underutilised as studies find there is low public awareness of their skills and services.<sup>81,82,83</sup> “More needs to be done to educate people about pharmacy and raise awareness of the expertise of pharmacists,” says Ms Passarani.

Some campaigns have launched for this purpose, including the ‘Stay Well Pharmacy’ campaign from the UK’s National Health Service (NHS),<sup>84</sup> while the American Association of Colleges of Pharmacy (AACP) have created the ‘Pharmacists for Healthier Lives’ campaign.<sup>85</sup>

The role of patient groups is also central to self-care initiatives.<sup>86</sup> Patient groups often have ‘expert patients’, those who have been self-treating a condition for some time and can bring their insights and mass knowledge back into the system.

“Patient groups are a very important conduit for this,” says Mr Sehmi, who adds that when policy is being drafted patient groups can review and contribute to the measures, find missing links and suggest policies of their own.<sup>87,88</sup> Patient group networks can also prove useful when disseminating policy education to target groups.<sup>89</sup> “If policymakers are implementing changes, it is through us that things will start happening. We have an enormous impact and can reduce some of the time frame and costs,” says Mr Sehmi.

## 03 Healthcare systems

Self-care will increasingly be built into healthcare policies and play an integral role in healthcare systems, especially with ageing populations and rising pressures on healthcare budgets. Importantly, though, strong healthcare systems, including primary care services that act as gatekeepers to healthcare systems, need to support people to self-care.

Across studies, self-care is associated with lower healthcare service utilisation and less wasted resources across primary and secondary care, thereby making more physician time available for more urgent cases.<sup>90,91</sup> The economic savings are difficult to quantify in their entirety but are generally considered to be significant for patients, healthcare systems and the broader economy.<sup>92</sup> Some calculations suggest potential healthcare system savings of US\$3.3bn if just 5% of American adults with one or more chronic conditions undergo self-management education programmes.<sup>93</sup>

# Evolution of self-care

For impact, system efforts are perhaps best focused on strong primary care services, which are essential to guide patients through the health system and avoid wasteful spending.<sup>94</sup> Without affordable and accessible primary care, patients may choose to directly seek emergency services, turn to alternative medications, or avoid medical care altogether. Countries that struggle to establish basic healthcare services experience these effects regularly, leading to more serious and costly health issues later.<sup>95</sup> In India, for example, a lack of primary care access has been linked with nearly 60% of poor children not having received recommended immunisations before the age of one.<sup>96</sup>

Healthcare systems can also work to ensure they are providing populations with the best quality information to self-care at the right touch points. "There is a big opportunity, but also a responsibility, for health systems to look at the information that people are accessing and figure out ways to let populations know that this information meets a standard in terms of being legitimate," says Dr Kelley. "I think that's a big question that will come up."

Some countries have worked to build out these services through public 24/7 phone lines that offer health advice for urgent medical problems or people unsure of what steps to take. For example, the NHS's 111 operators connect roughly 1.5 million callers per month with local services. Monthly reports show that about 20% are given self-care advice, potentially saving millions of medical visits per year.<sup>97</sup>

## 04 Medication

Medicines play an important role in self-care and healthcare systems. Whether self-initiated or following HCP recommendation, self-medicating ailments places less demand on formal medical services,<sup>98</sup> and all parties – patients, HCPs and third party payers – can benefit from cost and productivity savings.<sup>99,100</sup>

Drug regulators across the world typically create two or three levels of drug access:

- Prescription-only medicines, which require a prescription written by a qualified healthcare professional (mostly doctors, but can include dentists, nurses and others).
- Pharmacy-only medicines are OTC medicines that do not need a prescription, but are only available in a registered pharmacy. These medicines are usually behind the counter and require the sale to be under the supervision of a pharmacist. In some countries, like Australia and New Zealand, this category also includes a 'pharmacist-only' medicine category, which requires the pharmacist to consult with the consumer about need and the pharmacist may be required to make a record (name and address) of a sale.<sup>101,102</sup>
- General sales list medicines are OTC medicines that are available at general establishments unrelated to healthcare, including grocery stores and petrol stations.<sup>103</sup> This group of medicines does not preclude them from also being sold in pharmacies, where the public self-selects unassisted. In the US, this is the only version of OTC drug access.

# 20%

given self-care advice

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# US\$146bn

savings annually

A 2019 US study undertaken by CHPA, a trade association, and Booz & Company found that for every US dollar spent on an OTC drug, the healthcare system saves at least US\$7, totalling US\$146bn in savings annually. The majority of the savings is attributed to reduced medical visits and prescription drug costs.

OTC medicines generally can be used for common conditions and symptoms that can be diagnosed and addressed without medical supervision, such as pain, allergies, migraine, colds, heartburn and fungal infections.<sup>104,105</sup> The range of OTC products is also expanding, as formerly prescription-only medicines are shown to be safe to sell without medical consultation and relevant health literacy concerns are addressed.<sup>106</sup>

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Despite the benefits of convenience, cost savings and patient empowerment, safety is priority. And because drug regulatory bodies in each country differently weigh the risk of drug misuse, abuse, unintended side effects and other factors, there are major differences in approval and access worldwide, and various levels of pharmacist involvement required.<sup>110</sup>

As an example, a weight-loss drug, Orlistat, is among the many drugs operating under different access statuses. It is prescription-only in much of South America, but pharmacy-only in Europe, Singapore and Mexico.<sup>111</sup> In Australia, not only is it pharmacy-only but it has the additional restriction requiring that a pharmacist is involved in the sale.<sup>112,113</sup>

A report by The Economist Intelligence Unit in 2016 found that regulatory regimes for OTC medicines are highly inconsistent between countries and that effective harmonisation requires a holistic approach.<sup>114</sup> Mr Yasuda comments that to a certain extent the same drugs are used in every country, so international standards would enable easier access to medicines. "Based on this idea, in Japan there is an ongoing debate on establishing common standards for self-care drugs in coordination with other Asian countries," he says.

Regardless of drug classification, it is agreed by researchers that a good partnership and communication between consumers, HCPs and pharmacists is important to ensure that people are using medicines safely.<sup>115</sup>

## MOVES IN JAPAN



**In 2017 Japan introduced a self-medication tax deduction system that provides tax refunds for citizens who spend more than a set amount on designated OTC drugs each year. The goal is to promote OTC drug use, lessen reliance on prescription medication and relieve hospitals and clinics from patients with minor ailments. The demand for OTC medication is estimated to be increasing as a result.**<sup>108,109</sup>

# Evolution of self-care

## 05 Technology

The demographic shifts and strained healthcare budgets are a perfect storm forcing societies to think about the role of technology in self-care.

### Digital devices and apps

Self-care digital applications seem endless, especially for chronic disease management.

Diabetic patients, for example, can now use tools that monitor blood glucose levels and translate that into insulin doses – this is a significant change to a traditionally complex, manual task that is hugely important for managing diabetes.<sup>116</sup>

“I’m absolutely sure apps, wearables and other devices are going to transform healthcare,” says Dr Hudson. “There’s going to be far more use of digital technologies in supporting treatments, in deciding when to treat, who to treat, what to treat with, and monitoring the effects of treatments. It’s absolutely going to be critically important.”

Mr Yasuda adds: “The expected benefits of digital devices are that they will improve effectiveness as a result of preventing missed doses and providing care appropriate to one’s state of health.” However, he believes they will need extensive verification before they are introduced, to ensure the programmes run correctly.

From a general consumer standpoint, there may also be a massive evolution in wearable technologies or apps that can track a long-term condition (e.g. asthma or chronic obstructive pulmonary disease) or fitness (steps, calories, etc) that can play a key role in self-care.

“Passive monitoring is important,” says Mr El-Osta. “But apps and technology are only meaningful if they result in a sustained behaviour change and the step-wise adoption of healthy lifestyle behaviours. The wearable tech market is going to provide us with the opportunity to develop our personal health record, which in future could be appended to the electronic health records. However, the key is to make the personal health record available to the user in a way that is meaningful to them.”

Janet Woodcock, director of the Centre for Drug Evaluation and Research at the US Food and Drug Administration (FDA), points out that the early attempts at using digital devices were failures:

“A Fitbit, for example, can be put on a dog or kid at the park, making the patient look far more active, but creating problems when heart rates don’t align with an electrocardiogram ECG/EKG heart test. But we think that second, third, fourth generation attempts at this will eventually get it right, and people will be wearing all kinds of things. That will also occur in the OTC space. But until then we’re just going to need more data.”

And among medical professionals, digital devices have sparked a small but mighty shift in attitude. According to Mr Sehmi, many young doctors believe in self-care through digital health applications. “When they see what some applications can do, such as reminding diabetic patients to take their medicine, then they’re happy to give that space and to relinquish that control to the patient. Whereas the older doctors generally are not.”

A study by the American Medical Association also finds that doctors, particularly younger ones, are adopting digital health tools to help improve the physician-patient relationship, and improve adherence and convenience for patients.<sup>117</sup>

At the other end of the spectrum, digital or electronic healthcare records contain large datasets that are giving epidemiological insights that support healthcare or address safety concerns.<sup>118,119,120</sup>

### E-pharmacies

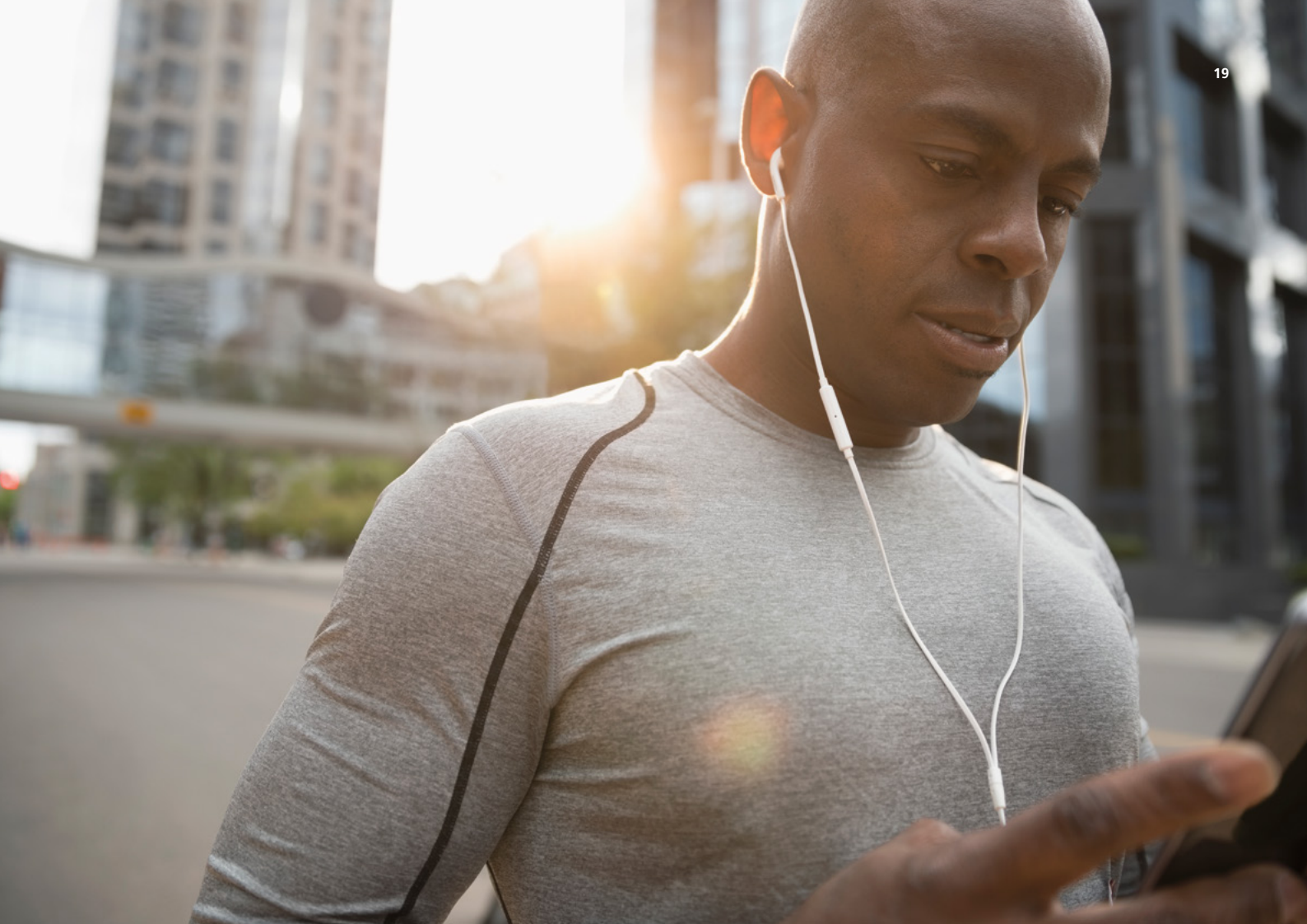
Online pharmacies, or e-pharmacies, are also growing rapidly. According to one estimate, the global online pharmacy market is estimated to reach US\$106bn by 2023, up from US\$29bn in 2014.<sup>121,122</sup>

The advantages are obvious: prices may be more competitive and patients could benefit from the accessibility and delivery, particularly for those in remote areas or with difficulty travelling, such as the elderly.<sup>123,124</sup> But the risks are equally clear: illegal online operations are thwarting the rules.

And according to The Alliance for Safe Online Pharmacies, a global non-profit for patient safety, all online searches for the phrase “buy medicine online” return links for illegal online pharmacies.<sup>125</sup> It has also been estimated that 96% of all global online pharmacies are acting illegally, which makes it a challenge for consumers who want trustworthy sites selling genuine products.<sup>126,127,128</sup>

These challenges and consumer safety risks place pressure on regulators to control information in a better way, monitor the safety and flow of medicines across borders, and tackle the risk of counterfeit or substandard medicines.<sup>129,130,131,132</sup>

In the next three chapters we conduct a comparative review of US, Europe and BRICS markets on self-care practices and policy. These three regions reflect varying political and economic systems, as well as different healthcare systems and public healthcare approaches.



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**Ian Hudson**

CEO, Medicines & Healthcare products Regulatory Agency (MHRA), UK

## CHAPTER 2

# Self-care approaches in the US



Policymakers are also encouraging self-care, and looking to remove unnecessary barriers.



Medication falls into prescription or non-prescription categories. The binary system increases accessibility but has less pharmacist involvement.



Experts expect medical devices and apps to play a significant future role. For instance, the Food and Drug Administration has already approved a pill with a sensor to remind patients to take medication.



E-pharmacies are on the rise, with education campaigns introduced to teach consumers the signs of fraudulent sites.



National guidelines support efforts to increase health literacy.



The US health system is increasingly turning to self-care practices.

# Self-care approaches in the US

## Healthcare system

The US health system is unique among developed nations. It is a complex, hybrid system of national, single-payer and multi-payer systems, funded by a mix of public and private financing mechanisms. The majority comes from private insurance, and most healthcare facilities are operated by the private business sector.<sup>133</sup>

Health outcomes are high in the US, but with patients and taxpayers footing the bill policymakers are under constant pressure to shed the country's rank as the world's highest spender on healthcare as a share of its GDP.<sup>134</sup>

In fact, of the nearly US\$3trn spent annually on healthcare, up to 69% may be heavily influenced by consumer behaviours such as poor diets and sedentary lifestyles.<sup>135</sup>

"It's not something we're necessarily proud of," says Mr Melville. "It's putting all sorts of pressure on budgets, whether they're federal budgets paying for Medicare or Medicaid, or they're state budgets that are paying part of the Medicaid. Or they are private-sector budgets as employers."

The pressures for the US to embrace self-care practices are mounting: half of American adults have at least one chronic condition.<sup>136</sup> Meanwhile, a majority of those 65 years and over have two or more chronic conditions.<sup>137</sup> The implications on the healthcare system's resources are severe, and the importance of chronic disease self-management and prevention has never been greater.<sup>138</sup>

US federal healthcare agencies are determinedly working to empower patients to self-care. The Centers for Disease Control and Prevention (CDC), an agency of the US Department of Health and Human Services (HHS), have recognised self-management support as one of four priorities in its Multiple Chronic Conditions: A Strategic Framework.<sup>139,140</sup> The HHS's strategy is to continuously improve evidence-based self-care management programmes, enhance their sustainability and improve their cost-effectiveness.

"I think self-care in some ways, at one point, was considered a trend and now I think it's the new normal," says Mr Melville.

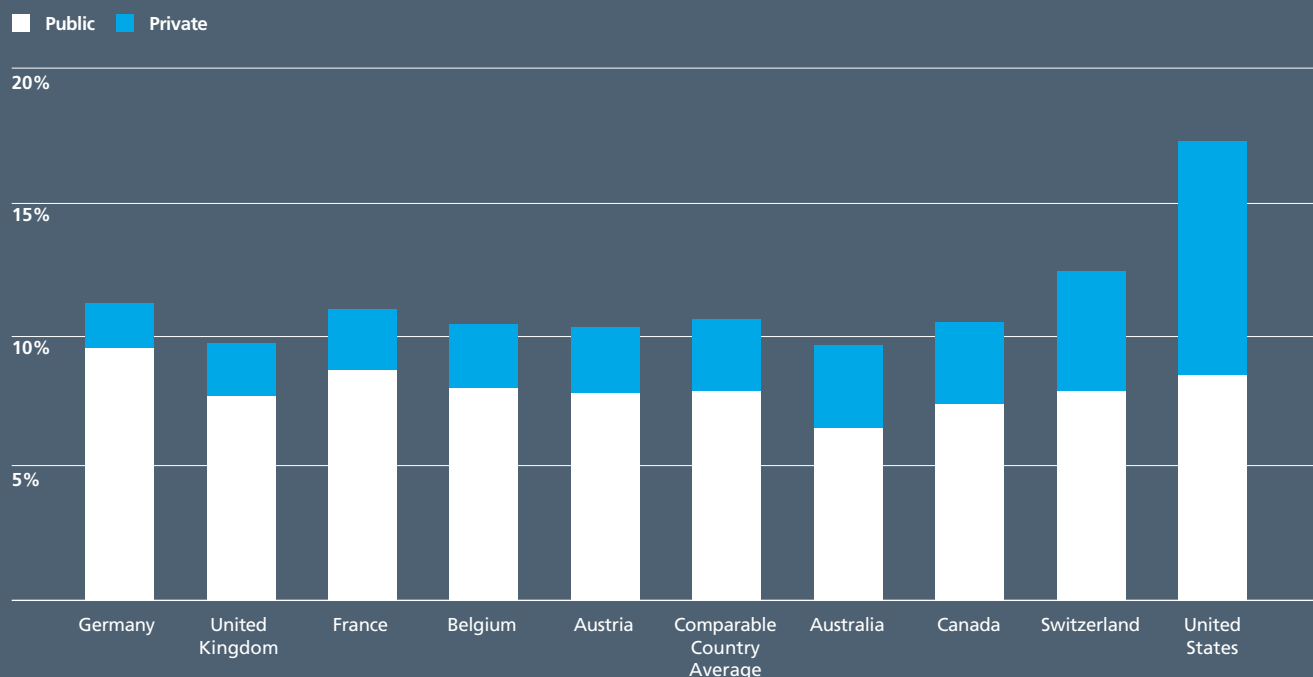
Unfortunately, healthcare services are not financially accessible to all of the US population: many Americans are uninsured or underinsured and therefore struggle to access services to support their needs.<sup>141</sup> For example, a 2015 study found more than half of people with a mental illness don't receive any mental health services. Financial concerns are the most prominent reasons.<sup>142,143</sup>

In 2014 the US Senate first participated in celebrating July 24th as International Self-Care Day. Each year the event aims to highlight to US policymakers the value of self-care and the role of non-prescription products as self-care tools.<sup>144,145</sup>

## Healthcare professionals

Physicians are the foundation of the US primary healthcare system. But as populations grow and medical school graduates increasingly move to more lucrative specialty and sub-specialty practices, the demand for primary care services is outpacing supply.<sup>146</sup>

## TOTAL HEALTH EXPENDITURE AS A % OF GDP BY PUBLIC VERSUS PRIVATE SPENDING, 2016



Source: Kaiser Family Foundation analysis of data from OECD (2017). "OECD Health Data: Health expenditure and financing: Health expenditure indicators", OECD Health Statistics (database).



In part to relieve this demand, American healthcare systems are looking to evolve the relationship between the providers and patients, shifting dynamics to empower patients to better engage in their care.

Some efforts by medical bodies to embed self-management support are clear. Notably, the American Medical Association developed a Physician Resource Guide to patient self-management support,<sup>147</sup> and the HHS has developed a toolkit for clinicians to support patients and their families with the day-to-day management of chronic conditions.<sup>148</sup> However, it is unclear what impact these have had. Further, it is not evident how much time is dedicated to self-management support skills and training in the medical curricula. Interviewees speculate it is low, and should be greater.

The squeeze on primary care has also given new consideration to preventative care, and pharmacists have been particularly identified as a potentially greater resource to address appropriate medication management and to act as gatekeepers for clinical services.<sup>149</sup> This is particularly evident in outpatient care for patients with chronic diseases that require monitoring.<sup>150</sup>

### Health literacy and hygiene initiatives

Statistically, the majority of the US population has a poor diet and little physical activity. These are both key drivers of the US obesity pandemic and contributors to chronic diseases, which have staggering human and financial costs.<sup>151</sup>

Numerous healthy eating and exercise efforts exist in the US at the federal, state and local level.<sup>152</sup> These include policies and incentive programmes to improve access to healthy foods, promote healthy school lunches, tax sugar consumption, and build cycling and pedestrian infrastructure.

Although these programmes have the potential to improve outcomes, the HHS recognises that health literacy is also foundational to promoting healthy people and communities. Here too, there is much work to be done. A 2003 national survey of health literacy – the first study of its kind and still the latest available national data – showed that health literacy is low.<sup>153,154</sup>

There are significant disparities between income, age, education, race/ethnicity and gender,<sup>155</sup> but overall some 36% of the adult population demonstrated basic or below-basic health literacy skills.<sup>156</sup> Only 12% of the population showed proficient health literacy. The limitations cost the country an estimated US\$106-238bn annually.<sup>157,158,159</sup>

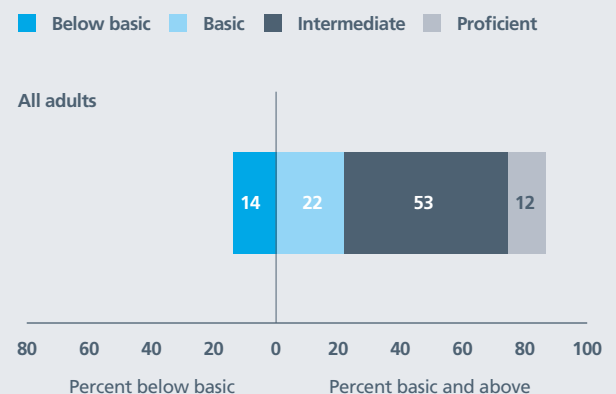
In 2010 the country took sweeping action to create a more health-literate America. This included signing the Plain Writing Act, a law that requires federal agencies to use plain language when communicating with the public, making it easier for everyone to understand and use health information.<sup>160</sup>

In the same year, the HHS released the National Action Plan to Improve Health Literacy.<sup>161</sup> The plan remains the latest blueprint for efforts to provide citizens with access to accurate, actionable health information, person-centred health services, and support for life-long learning to promote good health. The document details seven strategies that organisations can take to better develop and disseminate health literacy materials. The framework can also be used to add validity to any new and ongoing efforts in this area.<sup>162,163</sup>

Furthermore, the FDA is increasingly looking towards digital solutions to help tackle health literacy. “People may have trouble reading, but most people are able to watch television, or look at video screens,” says Dr Woodcock. “Some people can absorb information that way better than from reading. And if it’s done right, you may be able to get more information to people through video than you could through a written document or through an interactive screen. So, we’re looking at all those things, but we have to take the state of health literacy as it is.”

Hygiene, another pillar of self-care, while generally high in the US in terms of sanitation infrastructure,<sup>164</sup> shows room for improvement in lifestyle habits such as hand washing and daily dental care.<sup>165,166</sup> Efforts like CDC guidelines for hand hygiene for healthcare workers and the Oral Health Strategic Framework 2014–2017 aim to educate and prevent hygiene-related health disparities.<sup>167,168</sup>

### PERCENTAGE OF US ADULTS IN EACH HEALTH LITERACY LEVEL: 2003



**Source:** National Center for Education Statistics. (2006). “The Health Literacy of America’s Adults: Results From the 2003 National Assessment of Adult Literacy”. Available at: <https://nces.ed.gov/pubns2006/2006483.pdf>

# Self-care approaches in the US

## OTC medicines

The FDA believes that there is an important trend towards consumer participation in their own healthcare and, according to its website, “part of the agency’s mission is to keep up with the consumers’ wish to be more involved.”<sup>169</sup> Accordingly, many drugs that were once prescription-only are now available OTC in the US.<sup>170</sup>

The US has a unique binary medical classification system: medicines are either prescription-only or OTC general sales. There is no pharmacy-only category. This was set up in the 1950s.<sup>171</sup> When drug companies want to switch their drugs from prescription to OTC, they must consider three issues: benefit-risk comparison, consumer-friendly labelling, and how to make the drug a good choice as an alternative to prescription medication.

“OTC products are intended to supplement the medical options of the consumer, not substitute for a prescriber’s medical knowledge. If a health problem persists or worsens while using an OTC drug, consult a healthcare provider,” says the FDA.<sup>172</sup>

The broad OTC classification in the US means different types of OTC products – drugs, supplements, devices, or functional or medical foods – are often bundled in aisles right next to each other. Critics of the US binary system worry that pharmacists have a lesser role in counselling amid the product range. But advocates are quick to praise the benefits of broader access, convenience and cost-competitiveness of OTCs.

“Honestly, when a customer walks into a drug store, they are looking for relief, or treatment, or prevention, and they really don’t care about the regulatory distinctions,” says Mr Melville. “The common denominator is, it’s a healthcare product, it’s regulated by the FDA, and it’s selected by consumers without the intervention of a doctor, physician, pharmacist or medical professional.”

Dr Woodcock goes on to explain that, looking ahead, the FDA would like to broaden self-care opportunities in different ways in the US, including more OTC medicines. However, most medicines for straightforward and minor, diagnosable conditions have already earned OTC status.

Moving forward, each switch is likely to be pushing against concerning boundaries of health literacy and safety. For example, in 15 years the FDA declined three separate switch applications for cholesterol medications. The agency deemed hyperlipidemia too complicated for patients to self-diagnose and properly treat on their own.<sup>173</sup> By contrast, in the UK, the first brand of simvastatin (a cholesterol therapy), Zocor Heart-Pro, was switched to OTC in 2004 before it was taken off the market in 2010 because of limited consumer demand.<sup>174,175</sup>

But against this backdrop there may be a cultural change in the way switches are regarded by the medical community. Vaginal antifungals were among the earliest FDA switches in 2001. Dr Woodcock says there had been a tremendous amount of resistance over concern about whether patients would be able to correctly identify their symptoms and whether they might inappropriately use the drug for other indications.

However, there was very little to push back to the switch of nasal steroids for seasonal allergies in 2016. In that instance, HCPs felt that patients could diagnose their allergy symptoms correctly and follow the label for safe use, according to members of the FDA’s Division of Non-prescription Products.<sup>176</sup> The division adds that it helped that it was not the first drug of its class to switch, and other OTC antihistamines had switched with good results.

“The policymakers have to deal with reality,” acknowledges Mr Melville. “They have to weigh benefits against risks, and I think they do a pretty good job, although they tend to be a little more conservative than they need to be. But the reality is we have a very good system that makes products available that minimises misuse and abuse, and when those situations occur we as an industry can react, the FDA can react.”

Most US health insurers do not cover OTC medicines, and paying customers, particularly uninsured people, are more prudent about their choice of medicines, says Mr Melville. He explains that many will choose options that are more convenient and cost-effective than in markets where there is universal healthcare and where prescription drugs are covered.



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**Scott Melville**  
president and CEO,  
Consumer Healthcare Products Association (CHPA), US



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**Janet Woodcock**  
director, Centre for Drug Evaluation and Research,  
Food and Drug Administration, US

Some OTC benefits pilots are now going through the Centers for Medicare and Medicaid Services for those aged 65 and over. For example, a 2019 pilot by insurance provider Anthem, in partnership with retailer Walmart, whereby the insured person receives between US\$50 and US\$300 per quarter of OTC benefit to spend at Walmart.<sup>177</sup> “OTCs would be covered 100% under their insurance benefit,” says Mr Melville. “They are modelling to see if that will lead to reduced healthcare costs by the payer. We think that’s a really exciting development, and it will create some more pharmacoeconomic data that hopefully will underscore the value that OTC benefits can bring to the healthcare system.”

### The role of technology in self-care (apps, e-pharmacies and devices)

#### Apps and devices

The FDA hit the headlines in 2017 when it approved a prescription drug with an embedded sensor that sends a signal to a patient’s phone reminding them to take their pill.<sup>178,179</sup>

The FDA says that it encourages the development of mobile medical apps that improve healthcare and provide consumers and healthcare professionals with valuable health information. It adds that it has a public health responsibility to oversee the safety and effectiveness of medical devices – including mobile medical apps.<sup>180</sup>

“Self-care started to merge into the prescription environment,” explains Dr Woodcock, adding that the FDA is seeing a lot of interest in different apps and devices that will be associated with prescription drugs. “And we’re seeing a great deal of interest in attaching more digital information around OTC drugs as well.”

However, it is difficult for the FDA to maintain oversight over the proliferation of health in the consumer market.<sup>181</sup> To help manage the burden, most health apps do not require regulatory approval<sup>182</sup> and the FDA says its focus is on mobile, digital applications intended for use in the diagnosis, prevention, cure or mitigation of disease that could present a risk to patients if they do not work as intended or provide bad advice.<sup>183</sup>

FDA oversight of technology solutions will also consider whether people can understand the label, whether they can properly self-diagnose, whether they can properly select the treatment that is right for them, adds Dr Woodcock.

She explains: “We have had fairs where industries come in, they’ve brought in kiosks, they’ve brought in interactive tools and everything to help consumers walk through and help them make those decisions – in other words, sort of assist people who might not have a degree of health literacy. It would enable them to do that on their own, but most people can use a cell phone.”

#### E-pharmacies

E-pharmacy use in the US is on the rise, as it is in most global markets.<sup>184,185</sup> Lured by the convenience and possibility of cheaper medications, it is estimated by the FDA (in 2013) that nearly one in four American consumers purchase prescription medicines online.<sup>186</sup> And new businesses, including established companies like Amazon and traditional bricks-and-mortar pharmacies, are entering the online space – as well as illegal players. While this trend helps to enable self-care, the market shifts are opening up challenges for regulatory systems.<sup>187</sup>

To set the stage, at a federal level both the FDA and the Drug Enforcement Agency regulates and oversees physical and online pharmacies.<sup>188</sup> They are also further licensed at the state level, with minor differences in licensing rules among them.<sup>189</sup> Additionally, the National Association of Boards of Pharmacy (NABP), a non-profit to assist pharmacies in promoting public health, has been helping to monitor and review internet pharmacies in the US (and globally) since 1999.<sup>190,191</sup>

With some state exceptions, US online pharmacies are not allowed to sell prescription drugs to customers without a prescription from a doctor.<sup>192</sup> But several troubling reports suggest illegal online pharmacies are endemic, and more policing needs to be done. One NABP sampling of online pharmacies in 2015 found that 96% are illegal or not conforming to regulations.<sup>193</sup>

However, traffic on illicit US online pharmacies may be in decline, according to some reports.<sup>194,195</sup> This is in part due to cooperation from Google to downgrade ads by rogue players,<sup>196</sup> and by education campaigns that teach consumers signs of a fraudulent online pharmacy. One example is the FDA’s BeSafeRx, which is a national campaign to raise awareness of the dangers of buying prescription medicines from fake e-pharmacies.<sup>197</sup>

### SELF-CARE AND HEART DISEASE IN THE US



The American Heart Association (AHA) has recognised self-care interventions as a vital means of preventing and reducing the risk and incidence of cardiovascular diseases, including coronary heart disease.<sup>198</sup>

The AHA refers to a study of coronary heart disease patients, which found that rehabilitation trials focused on lifestyle modifications led to improved clinical outcomes and quality of life over those that focused solely on adherence to cardiac rehabilitation with no change to lifestyle.<sup>199,200</sup> The report concludes that the seeds of self-care behaviours are therefore best planted early in life, and efforts should be made to better incorporate self-care into the culture of society.

## CHAPTER 3

# Self-care approaches in Europe



European populations have various dependencies on formal healthcare systems and all can benefit from increasing self-care practices.



Traditional paternalistic approaches to healthcare are evolving, although the pace varies by nation.



The European Commission can make region-wide decisions on switching centrally approved drugs from prescription status to OTC after recommendation by the European Medicines Agency, but this is rarely used. But individual countries can also assess individual applications from companies on switches, so drug access can vary across nations.



European doctors often express frustration with the amount of unnecessary visits from patients.

European programmes exist to help patients boost health literacy for specific diseases.



Pharmacists play a significant role in self-care, but need wider recognition as a high-quality source of information.

Europe is a large market for health technology solutions. EU-wide associations are working to develop helpful solutions that overcome the fragmentation of national health systems.

# Self-care approaches in Europe

## Healthcare system

In most European countries public health services are jointly provided by federal, provincial and local authorities, and supported by a universal health and social insurance system.<sup>201</sup> Each European state defines its own health policy, delivers its own services and has its own regulatory bodies. Health outcomes are generally high, although there is wide variation in measured metrics, such as healthcare costs and incidence of non-communicable disease.<sup>202,203</sup>

According to Dr Hudson, the extent to which self-care is embedded in Europe's health systems varies from country to country, in part due to the range of cultural approaches of patients and doctors alike. "The traditional paternalistic approach to healthcare has moved on in different countries at different rates," he says.

Although there is no conformity among states, there are many initiatives that support European-wide self-care such as Self-Care Initiative Europe, a multi-stakeholder pan-EU network with a mission to embed self-care from policy to practice across health ecosystems in Europe.<sup>204</sup> Meanwhile, a 2017 report by the European Commission (EC) analysed member states' health systems and policy levers. It made suggestions to improve their effectiveness, accessibility and resilience, with a focus on health promotion, disease prevention and strong primary care services.<sup>205</sup>

Beginning in 2009, many European healthcare organisations participate in the annual Self-Care Week, a campaign to engage professionals, decision-makers and citizens to embrace self-care.<sup>206</sup> Within the UK alone, the number of participating organisations has increased from less than 50 to well over 600.<sup>207</sup>

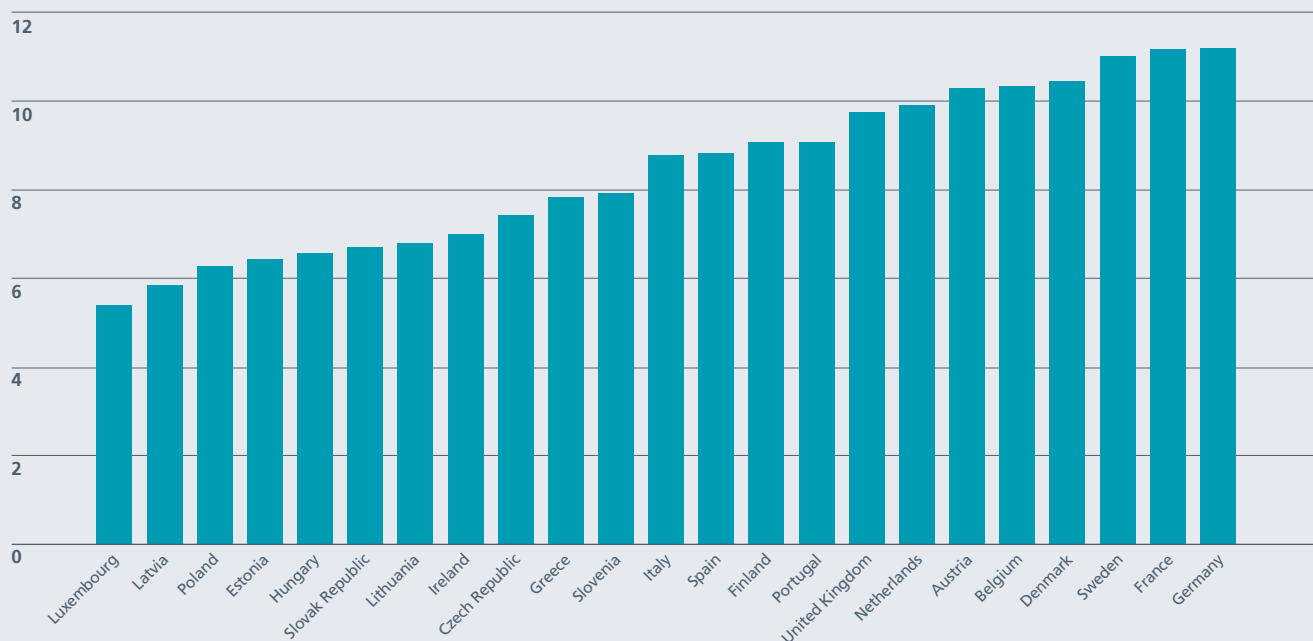
## Health literacy and hygiene initiatives

More than 20 European countries are preparing for a European health literacy survey in 2019. This comes on the heels of a 2009-11 EU health literacy project, which was the last time the EU general population was measured on the subject.<sup>208</sup>

It is hoped the results will be better this time around. The 2011 survey of eight European countries showed literacy varied across member states. Nearly half (47.6%) of the adult population showed limited health literacy, and 12.4% had the lowest level of health literacy (see table).<sup>209,210</sup> For example, in Germany 54% of respondents demonstrated limited health literacy, including difficulties understanding food and drug packaging information and the effects of health policy decisions on managing mental health problems.<sup>211</sup>

Hygiene, another area of self-care and a big focus of health literacy programmes, also shows room for improvement.

## EUROPEAN COUNTRIES' HEALTH EXPENDITURE AS A PERCENTAGE OF GDP, 2018 OR LATEST AVAILABLE



Source: OECD. (2019). Health spending (indicator). Available at: <https://data.oecd.org/healthres/health-spending.htm>

Although water and sanitation across Europe has increased, there are problematic disparities between rural and urban areas.<sup>212</sup> Foodborne diseases are found to be at high levels:<sup>213,214</sup> data collected from 18 European countries suggests that about 31% of foodborne outbreaks occur in private homes due to poor understanding of foodborne infections.<sup>215,216</sup>

A natural reaction across Europe has been to do more around hygiene and health literacy, particularly by making health literacy a priority across relevant policy areas.<sup>218</sup>

On national levels, the Scottish government, for example, released its second action plan, Making it Easier: A Health Literacy Action Plan for Scotland 2017–2025, which includes a number of improvement plans to embed health literacy in policy and practice and design services that better meet people’s health literacy needs. Efforts include health literacy training for HCPs, including health literacy in public school curriculums and working with patient group networks to develop health literacy responsiveness.<sup>219</sup>

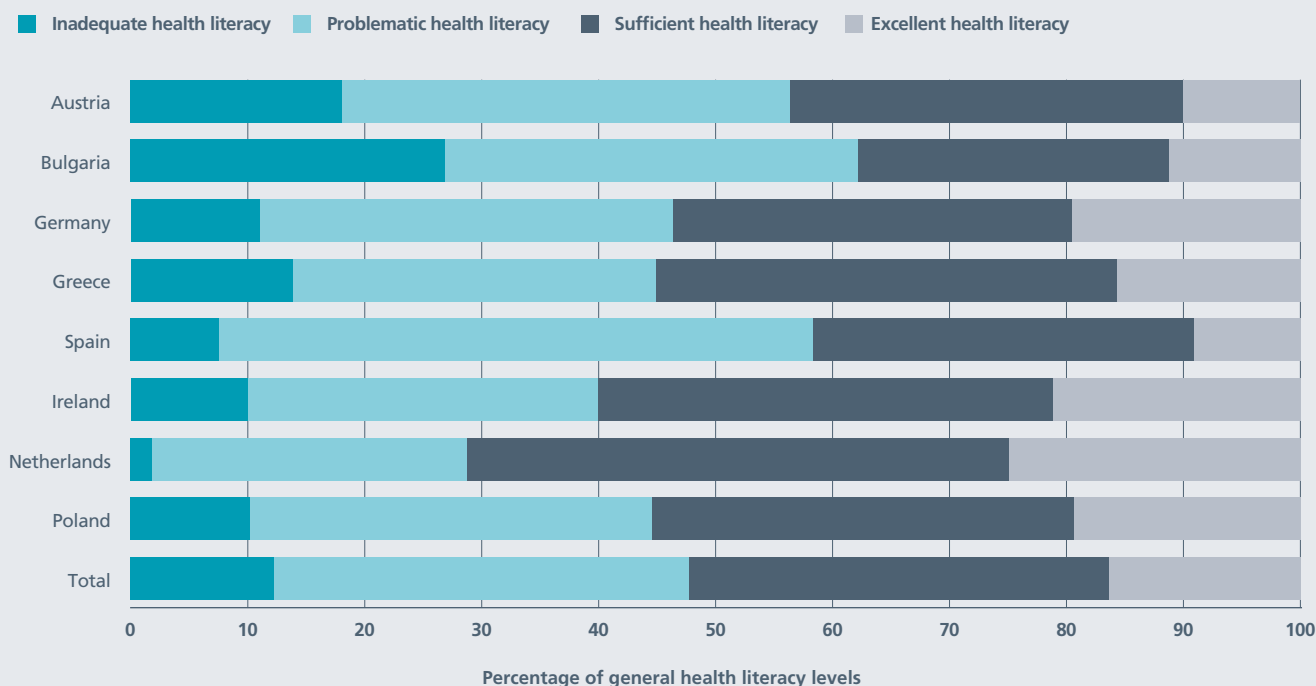
And in Austria, in 2014 the Ministry of Health released the policy National Health Target No. 3: Improving Population Health Literacy. Actions include the development of an Austrian web portal on trustworthy health information, and making low threshold health consultation available through a 24-hour telephone-based consultation service.<sup>220</sup>

There are also a number of examples across Europe of programmes that are helping patients boost literacy for specific diseases. For example, there are 102 diabetes self-management education programmes across the EU, according to a dedicated global database.<sup>221,222</sup>

And in Sweden, patients with chronic kidney disease and end-stage renal disease have benefited from a programme on self-dialysis. This programme trains patients on the equipment and keeps centres open 24/7, to be used when they want.<sup>223</sup> The process is more empowering for patients, and initial research suggests that self-dialysis patients are less likely to be hospitalised.<sup>224</sup>

“They do this literally thousands and thousands of times per year, so they know exactly how to do it,” says Dr Kelley. “It’s made a huge impact. It’s one of those programmes that other countries have been somewhat reluctant to adopt, but for me, it’s got big promise.”

### PERCENTAGE DISTRIBUTIONS OF GENERAL HEALTH LITERACY IN EUROPE<sup>217</sup>



Source: Health Literacy EU Consortium. (2012). Health literacy chart adapted from Comparative report on health literacy in eight EU member states. The European Health Literacy Project 2009–2012.

# Self-care approaches in Europe

## Healthcare professionals

### Doctors and nurses

The EC's 2017 State of Health in the EU report acknowledges that different skills and competencies are required for health systems to better deliver health promotion and disease prevention. "Patient-centred care and patient empowerment require general knowledge [from healthcare professionals] about self-care and self-management, but also 'soft skills' such as communication and teamwork," according to the report.

Yet the undergraduate training that many doctors and nurses receive around self-care enablement is variable, according to interviewees, and guidelines have not been firmly established.

Research is helping to guide how doctors can better help patients to self-care. For example, one European study identified 527 different self-care practices for the common cold among 2,724 patients. It concludes that doctors need to take a stronger role in understanding patients' discomfort during patient consultation in order to advise on best treatments and also take the opportunity to provide information about the disease.<sup>225</sup>

European doctors are also helping to drive a cultural shift towards self-care. For instance, in 2014 a UK doctors groups, the British Medical Association (BMA), pushed for a national healthcare strategy to relieve the burden on doctors and the health system.<sup>226</sup> And a 2017 BMA survey found that one in four GPs in England believe self-care is the most effective way of reducing workload.<sup>227</sup> The group emphasised the system "cannot afford for patients to have what they want when they want" and urged the government "to stop stoking unrealistic patient expectations".<sup>228</sup>

### Pharmacists

There is a high level of public trust in the ability of pharmacists to advise on non-prescription medicines.<sup>229</sup> And despite a general movement of OTC medicines to general store outlets, in many European countries pharmacists are still the main suppliers of OTC medications and therefore well positioned to facilitate consumer self-care.<sup>230,231</sup>

When European countries make the medicines switch from prescription-only to pharmacy-only and general availability, they often rely heavily on pharmacists to support the change and inform consumers. This is notable in recent switches of the erectile dysfunction treatment Viagra (sildenafil) and emergency hormonal contraceptives.

Indeed, pharmacists traditionally provide products that address acute conditions – such as sore throats, headaches, colds and gastrointestinal disturbances – but newer OTC drug reclassifications are increasingly medications for supporting long-term conditions. In some markets this has included triptans for migraines and orlistat for weight management.<sup>232</sup> Pharmacists are therefore being provided opportunities to play an even greater role in self-care management.

"Pharmacists are considered throughout Europe as a reliable source of high-quality information on health," says Ms Passarani. European pharmacists are well trained and equipped to offer a number of services, including health tests, flu vaccination, travel health advice and smoking cessation.

However, in some parts of the region, there are barriers to public awareness of their expertise, which leads to under-utilisation of their services. For example, an NHS England survey found that just 6% of parents with under-fives would go to a pharmacist before seeing a doctor or emergency services, and only 16% of adults would go to a pharmacist if they were unwell with a minor illness such as earache, diarrhoea or stomach ache.<sup>233</sup>

"We would like pharmacists to be recognised as an integral part of the healthcare team and an increase in the role of pharmacists through public awareness campaigns," says Ms Passarani.

She would also like to see the role of European pharmacists expand, as well as their ability to empower patients to self-care. "This means that pharmacists should be able to have access to the electronic health records of patients so that they can get a full picture, can provide better information and advice, and can better check whether the non-prescription medicines that the patient is asking for are suitable in relation to his or her conditions, and other medications that the patient is taking," Ms Passarani says.<sup>234</sup>

The PGEU also advises that pharmacists are given a leading role when self-care policies are created, because they have a unique insight into how people manage their medicines.<sup>235</sup> Professional pharmacist bodies, such as the Royal Pharmaceutical Society, also provide training materials for pharmacists around the introduction of a switched product.<sup>236</sup>

### OTC medicines

There are two general categories of OTC drugs in Europe: 'pharmacy-only medicines', which are sold under the supervision of a pharmacist; and 'general sales list' medicines, which can be sold from retail outlets other than pharmacies, such as supermarkets and petrol stations, without the supervision of a qualified HCP.

The European Medicines Agency (EMA) makes recommendations to the EC on medicines authorised through the centralised procedure as prescription or OTC, but the centralised procedure is rarely used for OTC switches. However, the decision as to whether the medicine should be available from pharmacies only or on general sale is up to the member state and should reflect the national situation.<sup>237</sup> Drugs can also be approved as OTC on a national basis, not going through the EMA's centralised procedure.

The OTC classification of certain medicines therefore varies among European states.<sup>238</sup> For example, amorolfine, a topical nail-varnish treatment for fungal infection of the toe and fingernails, is available OTC in France, Germany and Portugal but is prescription-only in Spain, Denmark and Finland, according to The Association of the European Self-Medication Industry, a not-for-profit organisation representing manufacturers of consumer healthcare products in Europe.<sup>239</sup>

Some studies also suggest that OTC availability reduces the demands on clinical services, but more knowledge is needed to improve utilisation.<sup>240,241,242</sup> A study funded by the PAGB, a UK trade association for OTC drug companies, found that some 32% of UK patients who went to see their GPs could have found an OTC product to help them, but 24% said they didn't have enough knowledge to do that.<sup>243</sup>





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**Ilaria Passarani**  
secretary-general, Pharmaceutical Group  
of the European Union (PGEU), Belgium

# Self-care approaches in Europe

While some experts think general sales OTC access should be widened, the PGEU is sceptical. Without professional guidance, they are concerned that many non-pharmacy distribution channels are under-regulated and do not necessarily improve accessibility.<sup>244</sup> “In all European countries, consumers can reach a pharmacy next to their home, so we don’t think that there are problems in terms of accessibility,” says Ms Passarani.

The differences in expectations are why, according to interviewees, from an OTC regulatory perspective it is unlikely that there will be complete harmonisation in the near future. “It isn’t simple to standardise across a jurisdiction like Europe,” says Dr Hudson. “There’s an awful lot of factors in play, whether it’s the number of categories of non-prescription medicines that there may be; whether there’s a consultation room in the pharmacy; the cultural attitude to healthcare; and the reimbursement aspects – can you get it free by going elsewhere, or do you have to pay?”

Mr Webber agrees: “In theory there could be organised, harmonised practice, but countries consider themselves unique and jealously guard their rights to regulate differently. It’s an ongoing challenge for the future.”

## The role of technology in self-care

The EMA has not yet approved such innovations as a tablet with sensors, but has taken a supportive position on future digital transformation in healthcare and aims to encourage innovation in human and veterinary medicines.<sup>245</sup>

## Digital devices and applications

European leaders are hardly resisting the digital revolution of healthcare. But with many apps made available and downloaded each year, regulation has become complicated. In early 2019 the EMA and national competent authorities announced new roles and responsibilities for regulating certain types of medical devices and applications.<sup>246</sup>

The EMA clarifies that, under European law, an app is considered a medical device when it has a medical purpose, including recording and registering data for further medical purposes, such as diagnosis, monitoring or treatment of a medical condition.<sup>247,248</sup> The app is then subject to regulations by medical device authorities in Europe. Furthermore, according to the EMA, medical apps and devices complying with European Product Directives and regulations should earn a CE marking, indicating the product may be traded in the European Economic Area.<sup>249</sup>

As the updated rules make clear, the EMA and national regulators split and share involvement in certain medical products and issues. Sometimes products are ‘borderline’ and a decision has to be made over which regulatory framework applies.<sup>250</sup>

Safety and privacy are also hot topics among European agencies. The EC has been helping to push initiatives that strengthen digital access and security across member states. This includes recommendations for EU-wide secure sharing of digital health records to assist citizens that move between nations.<sup>251</sup>

The European Institute of Innovation and Technology, a consortium of businesses, research centres and universities, is also working to overcome the fragmentation of different health systems and create new health technology products for market, particularly around vitality and ageing.<sup>252</sup>

Mr El-Osta adds that there is a vision in the EU to deliver a personalisation agenda where individuals are empowered with technology. This would result in what policymakers call the ‘e-citizen’, who is able to routinely interact with government and services or manage personal health budgets, hospital appointments and other services including passport and driving licence appointments.



It is recognised that e-pharmacies have an important role to play in the future of healthcare. They certainly will have their place in terms of rural communities, or people on repeat medications, or people who are very busy and want an easier way to order.

### Ian Hudson

CEO, Medicines & Healthcare products Regulatory Agency (MHRA), UK

# 10,000

sites shut down

To help address the illicit proliferation of e-pharmacies, under the Falsified Medicines Directive, the EC introduced a digital logo for its member states to vouch for the authenticity of the websites and guarantee the safety of the products. In the UK alone, the MHRA reported that it has shut down 10,000 illegally operating sites since 2015, but publicly stated in 2017 that it will be “completely impossible” to control them all.

“Improvement in health and digital literacy will promote self-care in the future and the rational use of products and resources, including OTC medicines and ‘lifestyle medicine approaches’ to prevent, delay or self-manage common everyday and long-term conditions.”

### E-pharmacies

In most European countries, some pharmacies already have an online presence, with the provision of home delivery services. Some e-pharmacies also provide an online doctor consultation service.<sup>253</sup>

“It is recognised that e-pharmacies have an important role to play in the future of healthcare,” says Dr Hudson. “They certainly will have their place in terms of rural communities, or people on repeat medications, or people who are very busy and want an easier way to order.”

But in the acceptance of e-pharmacies the European landscape appears divided. In many European countries, the culture is traditional around maintaining individual and often family-run pharmacies. For example, in France and Spain all pharmacies must be owned by pharmacists, and chains are banned.<sup>254</sup> But in other countries, like the UK, large pharmacy chains make up nearly 50% of the market,<sup>255</sup> and they can often offer a wider range of services, although this is not to say that the smaller players do not provide quality services.

Amazon may also be changing the response to e-pharmacies. The internet giant is developing a pharmacy business in the US as part of its move into the home delivery market,<sup>256</sup> and European pharmacies are seeing this as a threat. Some are forming e-pharmacies in response. “This is a serious opportunity,” thinks Mr Webber. For example, Zur Rose, a large Swiss-based e-pharmacy, has made acquisitions in Germany, Italy and Spain, and is looking for partners across Europe.<sup>257,258</sup> “We’ll see this European e-pharmaceutical trend continuing, and it will be one to watch,” he says.

The important thing, Dr Hudson cautions, is that just like ordinary pharmacies, e-pharmacies are regulated properly and consumers can be assured that they are legitimate.<sup>259</sup> In the UK, for example, pharmacies registered with the General Pharmaceutical Council can opt to operate online but have a physical presence. Therefore, consumers can be assured that they are regulated properly and are legitimate.

To help address the illicit proliferation of e-pharmacies, under the Falsified Medicines Directive, the EC introduced a digital logo for its member states to vouch for the authenticity of the websites and guarantee the safety of the products.<sup>260</sup> In the UK alone, the MHRA reported that it has shut down 10,000 illegally operating sites since 2015,<sup>261</sup> but publicly stated in 2017 that it will be “completely impossible” to control them all.<sup>262</sup>

At the end of the day, interviewees agree that there will always be a key role for people to go into their local pharmacy and get healthcare advice from their pharmacist, and that e-pharmacies are a diversification of the healthcare system and an addition to the way we manage care.<sup>263</sup>

## MIGRAINE RELIEF ACROSS THE EU



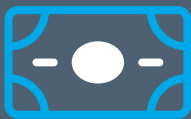
**Migraine is a common, chronic neurovascular disorder characterised by severe and debilitating headaches that can last from hours to even days. It affects nearly 15% of Europeans, with significant economic impact to patients and health systems.**<sup>264,265</sup>

The European Federation of Neurological Societies has issued guidelines on the treatment of migraines. These provide strategies for healthcare professionals to accurately diagnose and manage the condition, but do not include direction around self-care. Various European countries have also published their own guidelines on migraine prevention and management, such as the UK, the Netherlands, Spain, Germany, Switzerland and Austria.<sup>266,267</sup> The UK’s National Institute for Health and Care Excellence guidelines notably include self-care advice for patients, including encouraging the patient to use a headache diary.<sup>268</sup>

Most national plans incorporate recommendations for non-drug treatment, including behavioural and psychological techniques, which are considered an important – and complex – part of headache management.<sup>269</sup>

## CHAPTER 4

# Self-care approaches in the BRICS



BRICS (Brazil, Russia, India, China and South Africa) healthcare systems struggle to raise sufficient funds to support universal health coverage, particularly in rural areas. The demand burden makes it challenging to impart self-management advice in a clinical setting.



For a healthcare system to work effectively, and empower people to self-care, it must have a strong, accessible primary care system. This is still a work in progress in the BRICS. Policymakers could benefit from greater awareness and commitment to promoting self-management of health problems and diseases.



Many BRICS populations rely on traditional medicines, or a mixture of traditional and modern medicines. Policymakers can help ensure that more relevant, qualified and trustworthy information is made available to patients.

Large-scale initiatives are helping to boost hygiene access and practices, which supports self-care, such as China's 'toilet revolution', India's nationwide Clean India programme, and various campaigns in Brazil.



The regulation of medical devices and applications is an evolving landscape. Regulatory bodies are largely overwhelmed and developing new rules and parameters for medical technology.



The e-pharmacy market is expanding, and regulators are overwhelmed by efforts to regulate and verify the legitimacy of its many actors.



Health literacy could be boosted significantly in the BRICS. It has been exacerbated by gaps in education attainment and access to health facilities.



Healthcare professionals are not widely trained to empower patients to self-care.



BRICS are one of the fastest-growing OTC medicine markets. Regulatory systems are updating their frameworks to improve patient safety and fast-track medications for market.

# Self-care approaches in the BRICS

# 40%

## global burden of disease

BRICS is the acronym for an international association of five major emerging non-Western national economies: Brazil, Russia, India, China and South Africa. Together they represent around 40% of the world's population and about 40% of the global burden of disease.

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In these nations, living standards are rapidly improving and health needs are constantly increasing, both in terms of formal services and self-care.

As with many emerging countries, BRICS are experiencing public health challenges that typically come along with improved economic performance: a growing shift towards more NCDs, including cancers, and cardiovascular and respiratory diseases.<sup>272,273</sup>

With the exception of South Africa, NCDs are the biggest problem facing BRICS countries and the incidence of NCDs is increasing, even as infectious diseases are being brought under control.<sup>274</sup> The shift is creating more demand for chronic care and greater need for individuals to take greater responsibility for their care.<sup>275</sup>

### Healthcare system

Healthcare systems and regulatory bodies vary considerably among the BRICS nations, yet each has committed themselves to reform programmes with the goal of achieving stronger health coverage.<sup>276,277,278</sup>

Yet common challenges are clear: each has issues raising sufficient funding for public spending on healthcare; has difficulty ensuring equitable access to health services; is challenged to manage changing demographics and disease burdens; has issues addressing social and cultural determinants of health; and each healthcare system places ever-increasing value on self-care.<sup>279</sup>

At a high level, each nation's healthcare system is described in summary here:

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## Brazil



- Brazil's free public healthcare system (known as Unified Health System or Sistema Único de Saúde (SUS)) has been progressing towards a universal health coverage model since its conception in 1988.
- The SUS is funded by the state, both at federal and local levels. Over time, the SUS has made substantial progress in increased access and delivery of public health programmes. About a quarter of the population has private insurance coverage.<sup>280</sup>
- The SUS is threatened by gaps in its organisation and governance and from economic and political crises and austerity policies that have capped public expenditure growth.<sup>281,282</sup>
- Large regional disparities exist in access to healthcare services and health outcomes, with poorer regions and lower socioeconomic groups most disadvantaged.<sup>283</sup>
- Life expectancy in Brazil has grown from 54 in 1960 to 76 in 2016,<sup>284</sup> while birth rates have lowered – consequences of Brazil's improving economy and healthcare system – but the demographic shift is adding economic pressure and threatening healthcare sustainability.<sup>285,286</sup>

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## Russia



- Russian citizens and residents are entitled to free public healthcare through the country's Obligatory Medical Insurance system. The minister of health oversees Russian healthcare, which is dominated by public providers and state-run insurance systems.
- The public system is overburdened by demand. A Bloomberg report ranked Russian healthcare last out of 55 developed countries based on the efficiency of state healthcare systems, for reasons including lack of government funds, poor organisational structure, and significant gaps in infrastructure across the country.<sup>287</sup> Recent improvements have been considerable but unevenly distributed.<sup>288</sup>
- The average Russian population is ageing and has fewer children, which increases the average number of long-term chronic conditions and puts pressure on public spending per person. Concurrently, a rising middle class is placing more pressure on high quality, Western-style healthcare and medicines.<sup>289</sup> Considering its growing wealth, some commentators are also saying Russia's life expectancy should be higher.<sup>290</sup>

# Self-care approaches in the BRICS

## India



- India has a mixed healthcare system, inclusive of public and private providers. The governance and operations of the health system are divided between the federalised system and the state governments. The Union Ministry of Health & Family Welfare is responsible for the implementation of various programmes on a national scale, while areas of public health, hospitals and sanitation come under the purview of the state.<sup>291,292</sup> In September 2018, India launched a new health plan aiming to provide health insurance to 500 million people in the low-income bracket and cover 40% of its population.<sup>293</sup>
- Most private healthcare providers are concentrated in urban areas. By some reports, private healthcare sector spending is higher than public healthcare – outlining the disparity of national coverage. Healthcare expenditure is still largely paid out-of-pocket by patients rather than through insurance.<sup>294,295</sup>
- Updates to the National Health Policy in 2017 address the need to focus on the growing burden of NCDs, the need to address rising healthcare costs, and to improve primary and preventive care.<sup>296,297</sup>
- India is experiencing rapid urbanisation, rising longevity and lower birth rates, and rapidly rising rates of chronic diseases such as cardiovascular diseases, cancers, diabetes and chronic respiratory diseases.<sup>298</sup>

## China



- China has undergone complex healthcare reform in recent history, which has ultimately led to the expansion of the basic medical insurance network, strengthened financial investment in medical treatment for rural areas, public hospital reform, and the strengthening of primary care.<sup>299,300</sup>
- The Chinese government's position is that it provides medical coverage for most citizens. While the majority of the population has some form of coverage under the national social insurance plan – which includes distinct health insurance schemes for urban and rural populations – the reality of healthcare delivery is more complicated and uneven.<sup>301</sup>
- In October 2016, the Chinese government announced the 'Healthy China 2030' blueprint, which has the goal of providing universal health security for all citizens by 2030.<sup>302</sup> In December 2017, China introduced a draft National Health and Health Promotion Law that makes access to basic healthcare services a legal right.<sup>303</sup>
- China struggles to address the large healthcare demand gap due to an ageing population and lower birth rate, severe disparities in accessibility and quality of healthcare, growing urbanisation, proliferating lifestyle diseases, rapidly increasing consumer wealth, and the advancement of universal healthcare insurance.<sup>304,305</sup>

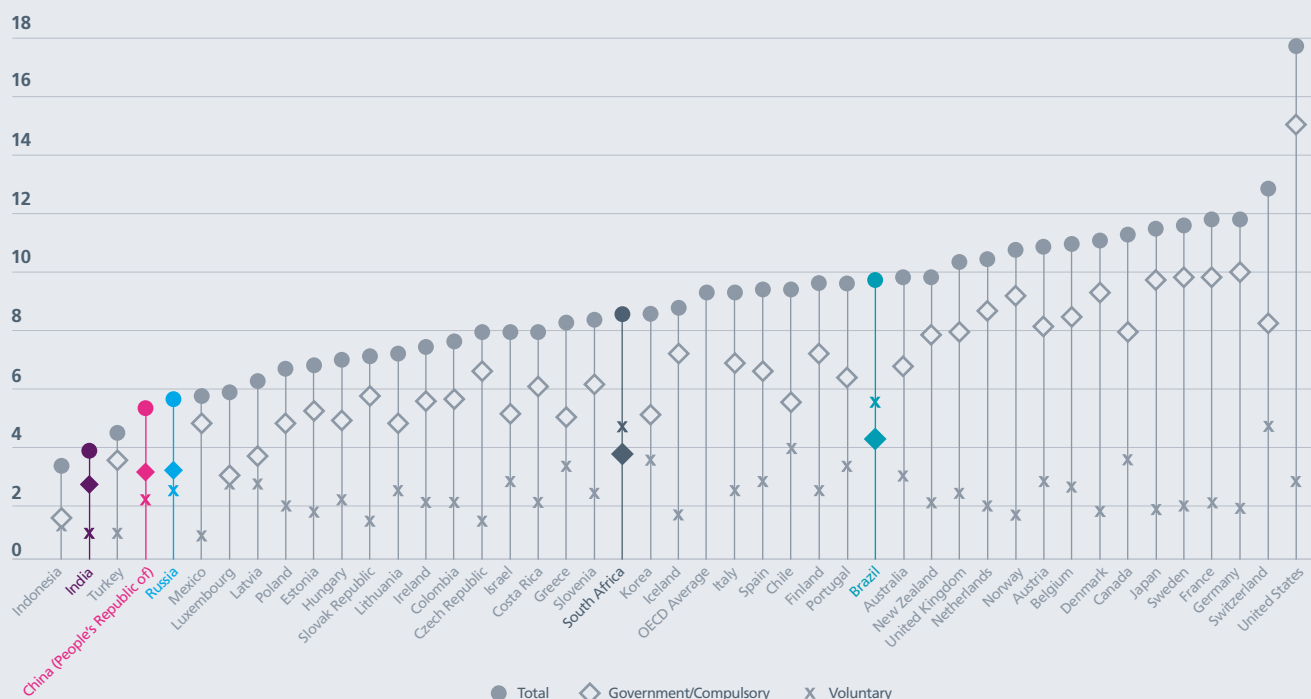


## South Africa



- South Africa's Constitution guarantees every citizen access to health services.<sup>306</sup> The health system comprises an under-resourced and overused public sector and smaller but well-funded private sector.<sup>307</sup> The National Ministry of Health is responsible for policy development and coordination.
- Although the private sector serves only 16% of the population, it accounts for around half the total healthcare spending in the country. The remaining majority of the population is served by public services.<sup>308</sup>
- The public sector has noted disadvantages such as variable quality, long wait times, rushed appointments, old facilities, and poor disease control and prevention practices.<sup>309</sup>
- South Africa is planning a universal healthcare fund: the National Health Insurance. Draft law was published in June 2018 and the government hopes to secure its passage in 2019, with a view to achieving its implementation by 2026.<sup>310</sup>
- Its implementation will involve a massive reorganisation of the current health system with the aim to better achieve sustainable, affordable access to healthcare services for all citizens.<sup>311,312,313</sup>
- South Africa has the most rapidly ageing population in Africa. It is experiencing rising life expectancy, lower birth rates and a growing middle class.<sup>314,315,316</sup>

### HEALTH SPENDING: TOTAL/GOVERNMENT/COMPULSORY/VOLUNTARY, % OF GDP, 2018 OR LATEST AVAILABLE.<sup>317</sup> BRICS VERSUS OECD COUNTRIES



Source: OECD. (2019). Health spending (indicator). doi: 10.1787/8643de7e-en

# Self-care approaches in the BRICS

## Primary care: the primary concern

For a healthcare system to effectively empower people to self-care, it must have a strong, accessible primary care system – the first line of defence for prevention, management of short-term and long-term conditions and injury.<sup>318</sup>

Among BRICS nations, this provision is often a challenge. These nations share issues of a patchy, poorly functioning primary care system. Access is often difficult and rife with inequalities, especially in rural and poorer areas. Furthermore, primary care facilities are often overcrowded, understaffed and under-resourced, and doctors are not always well trained.<sup>319,320,321,322,323</sup>

China, for example, does not yet have a nationally strong primary care system, and people often visit hospitals to see specialists, even for self-treatable ailments (e.g. fever, headache).<sup>324</sup>

The Economist Intelligence Unit's report on patient-centred care found that China did poorly in terms of accessibility to primary care or family doctor services.<sup>325</sup> And in a 2018 *New York Times* article, Mao Qun'an, the spokesperson for the National Health and Family Planning Commission, acknowledged that the hospitals, which are understaffed and overwhelmed, could no longer meet the public's needs. "If you don't get the grass roots right, then the medical problems in China cannot be solved," Mr Mao had said. "So what we're doing now is trying to return to the normal state."<sup>326</sup>

Dr Huiliang Bai, council member of the International Self-Care Foundation in China, explains: "China is a developing country. For historical reasons, development in developed cities and remote rural areas is still very unbalanced. Many high-quality medical resources are concentrated in cities... However, the Chinese government has been working hard to solve this problem."

In Brazil, underfunding of local SUS family clinics and health centres often push patients to 'second-assistance' hospitals, which are intended to treat common illness and carry out minor operations. However, these are often overwhelmed by patients who should have been treated elsewhere, or should have been able to self-care.<sup>327</sup>

Primary care is widely variable in India as well, according to Professor K Srinath Reddy, president of the Public Health Foundation of India, an initiative to strengthen training, research and policy development related to India's public health systems. "The design after independence [in 1947] was mainly to look at primary healthcare in rural areas because it was assumed, rather naively, that urban areas would have sufficient supply of doctors to have people access them... However, this has not developed as well in terms of human resources, infrastructure and equipment in all parts of the country, particularly because of poor public financing. There are some states where primary healthcare is very well developed, but in many parts primary healthcare is still quite deficient."

"The design exists," Dr Reddy continues. "There has been an attempt over the last ten years to try and improve access and the quality of primary health: much needs to be done." He notes that the Indian government's programme, announced last year, puts more emphasis on developing primary healthcare in the rural areas. "And an urban health mission is now to be advanced. But it has not received adequate funding yet."

## Self-care in policy

Across BRICS nations there is an increasing emphasis on health in terms of healthy lifestyles, including diets and physical activity<sup>328,329,330,331,332,333,334,335,336</sup> as well as hygiene, as referenced later in this chapter.

But, according to Dr Reddy, in terms of self-management of health problems and diseases, there is generally not much awareness or commitment on behalf of policymakers.

The existing, dedicated self-care programmes predominantly concentrate around long-term, non-communicable conditions such as diabetes, hypertension and chronic lung disease.<sup>337,338</sup> Self-care programmes have also played a role in promoting HIV/AIDS self-testing, to tackle the gap in HIV testing.<sup>339</sup> Beyond such pockets, there is clearly more room for improvement at a general level, particularly in the resource-squeezed public sector.

There are signs of future improvement. For example, China's health agenda, Healthy China 2030, which aims to provide equal access to health services for every citizen by 2030, was drafted with a special concern given to patient engagement at the individual, household and community level. This is in the hope that patients will be more empowered and activated through an individualistic approach.<sup>340</sup>

And in Brazil, a 2017 Consolidation Ordinance by the Ministry of Health mentioned the transition of professional care towards self-care as one of the key issues for solving the problems of the Health Care Network for supporting people with chronic diseases.<sup>341</sup> Furthermore, Brazil's National Primary Health Care Policy establishes that individuals' autonomy is one of the main purposes for self-care outreach, explains William Dib, director-president of the Agência Nacional de Vigilância Sanitária (ANVISA) in Brazil.

## Healthcare professionals

The large geographic footprints and rising urbanisation in BRICS countries is widening the urban-rural distribution of qualified HCPs.<sup>342</sup>

India and South Africa, for example, fare poorly against the international recommendation of one doctor for every 1,500 to 2,000 people (see chart on page 42), but these figures look worse when they take into account rural and urban divide, or private versus public coverage.

Consider that in South Africa 70% of doctors work full-time in the private sector, which services only the 16% of South Africans with private health insurance.<sup>343</sup> And Russia, which on average has sufficient doctors per population, is also facing other workforce issues. According to a 2016 report, most primary care physicians are on average 60 years old, and the supply of GPs is not keeping up with demand, as many medical students are being lured by higher paying specialist positions.<sup>344,345</sup>

And, in many of these nations, populations and healthcare providers still hold paternalistic expectations of public healthcare systems. In some cases, this excludes the patient from their diagnosis and from participating in the clinical decision-making process.<sup>346,347,348,349</sup>



#### CHINA'S MEDICAL AND HEALTHCARE SYSTEM REFORM



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In 2016 China's president, Xi Jinping, delivered an important speech at the National Health and Wellness Conference, where he proposed "striving to comprehensively ensure the people's health for their whole life", "advocating a healthy and civilised lifestyle and asserting the concept of good health, transforming the focus from being the treatment of disease to people's health, to establish a sound health education system, improve the health of the whole population and promote the fusion of fitness and health for the whole population."

# Self-care approaches in the BRICS



Pharmacists play a big role, there's no doubt about it. There is an increasing demand that we must regulate the role of the pharmacists and give them some authority for [writing] prescriptions, but that's not yet happened.

**K Srinath Reddy**

president, Public Health Foundation of India (PHFI), India

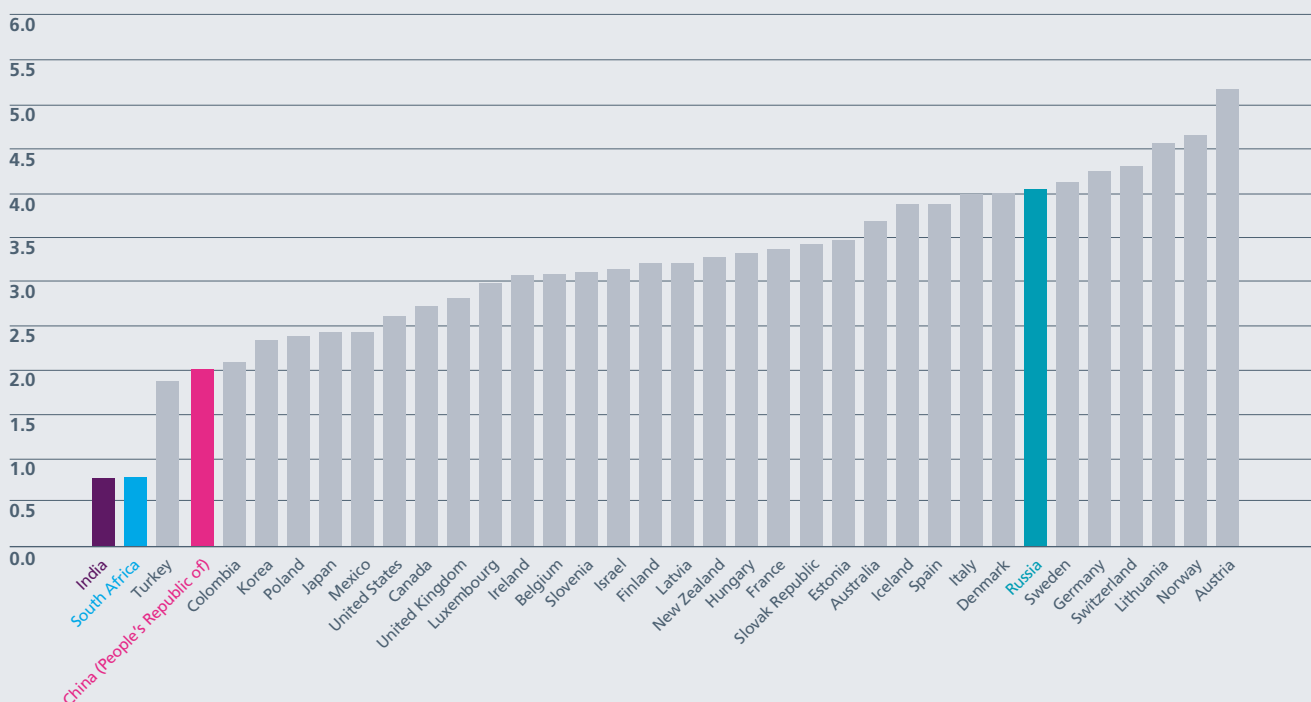
HCPs are also not widely trained to empower patients to self-care, explained interviewees. And at the public level, doctors are so overwhelmed with the number of patients that they do not have the time during consultations to engage them in a conversation about their condition and how they can participate in self-management.

"I would say truthfully that the paternalistic mode still persists in India," says Dr Reddy. "There is a minority which is expanding, which believes that it's beneficial if the patient is aware and participates in the process of management. But right now, I would say the more physician-dominated, paternalistic mode is the norm."

Pharmacists are playing a growing, significant role in self-care education, in addition to providing medication management across the continuum of care. The evolving pharmacy role, in part, has been spurred on by the absence of readily available, affordable clinical care, which is also driving demand for OTC medicines.<sup>350,351,352</sup>

"Pharmacists play a big role," says Dr Reddy. "There's no doubt about it. There is an increasing demand that we must regulate the role of the pharmacists and give them some authority for writing prescriptions, but that's not yet happened." He adds that India's Ministry of Public Health is exploring further responsibilities where it can play a role in providing medication, particularly in underserved areas where physicians are not easily available, or take prescriptions by telemedicine.

**NUMBER OF DOCTORS PER 1,000 INHABITANTS, 2017 OR LATEST AVAILABLE. BRICS VS OECD COUNTRIES. INDIA AND SOUTH AFRICA FARE POORLY AGAINST THE INTERNATIONAL STANDARD OF ONE FOR EVERY 1,500 TO 2,000 PEOPLE. (BRAZIL DATA NOT AVAILABLE)<sup>353</sup>**



And in China, national drug policies, medical needs of the masses and big national health strategies are placing new demands on pharmacy services. According to Mr Bai, “In terms of the development of universal health, ensuring that consumers can buy safe and effective drugs is just a basic function for the consumer-facing pharmacy; having capacity to provide products related to healthcare, developing a health-focused service industry is an important channel for the advancement of retail pharmacies and providing more pharmacy service professionals are key.”

He adds that some pharmacies in the country are already attempting to promote health and that this type of evolution is constantly emerging. “For example, GuoDa Drugstore has launched a professional service for chronic diseases and has established a series of services and systems for the management of patients with diabetes.” Additionally, “NanJing Pharmaceutical launched the construction of the Smart Garden project, creating a medical information service platform whereby residents’ health records are digitalised, thereby effectively integrating pharmacy and information data, providing free chronic disease detection, health talks and education and free Chinese medicine consultation.”

### Health literacy and hygiene initiatives

#### Hygiene

Populations at extreme levels of poverty or far from urban centres may lack basic access to clean water, effective sanitation, waste management, reasonable housing conditions and good schooling. These factors set the scene for poor domestic and personal hygiene, which can lead to the transmission of cholera and diarrhoea.<sup>354</sup>

Water, sanitation and hygiene programmes have been significant in enacting change within BRICS nations, often with the political goal of reaching Sustainable Development Goal targets for water supply and sanitation set by the United Nations.<sup>355</sup>

Efforts are highlighted by China’s ‘toilet revolution’, India’s nationwide Clean India programme, and various campaigns by the National Sanitary Surveillance System under Brazil’s Ministry of Health and by the South African National Department of Health.<sup>356,357,358,359</sup> Each involves both a cultural and infrastructure change backed by investment for construction and education programmes – particularly around toilet facilities and hand-washing stations.

Progress is variable, but on the right course. For example, the number of South African households using bucket toilets or without sanitation facilities declined from 12.6% in 2002 to 3.1% in 2017.<sup>360</sup> According to one 2018 report, 69% of South Africa’s rural population now has access to at least basic sanitation.<sup>361</sup>

Other nations have more room to improve. India, for example, continues to face many obstacles to personal and domestic hygiene, including poor hand hygiene, poor food and water sanitation and open defecation, and even poor oral hygiene, which contribute to oral diseases that affect 60–90% of the population (particularly in rural areas).<sup>362</sup>

Dr Reddy says the Clean India programme (known as *Swachh Bharat*) has meant a major push on sanitation and hygiene in the last few years in the country.<sup>363</sup> “The mission was started because

it was felt that India’s high levels of open defecation were a major health hazard,” he explains. “The occurrence was very high even compared to neighbouring South Asian countries.” Efforts are also being made under the programme to improve sanitation in urban areas in terms of garbage disposal and clean water.

He adds that a lot of government money has been spent not only on constructing toilets, but also in trying to promote media messaging around this.

#### Health literacy

General health literacy in BRICS nations has been exacerbated by gaps in education attainment and access to health facilities. This leads to preventable health inequities.<sup>364</sup> For example, a study of patients with hypertension in China found that cases are rising at a higher rate in rural areas, and that patients there have lower health literacy and poorer self-management ability than their urban counterparts.<sup>365</sup>

Although few to no national surveys have specifically explored health literacy rates in the general populations of BRICS nations, it is understood to be poor.

In the case of Brazil, no literacy surveys have been conducted and the government does not have any public policies that specifically recognise the importance of health literacy for improving the population’s health conditions.<sup>366,367,368,369</sup> No national surveys exist within Russia, China or South Africa either. But, tellingly, one local South African study found a third of the 120 participants reported always requiring help when reading general health information, and 82.5% were categorised as having either inadequate or marginal health literacy.<sup>370</sup>

More needs to be done around health literacy and it needs to be fast-tracked, says Dr Reddy. “This needs to be done both by public agencies and also by the health professionals themselves...there is much to be desired in the sense that even if people passively comply with the instructions provided by the doctor, it is not done with a degree of knowledge and self-awareness of the condition that could qualify for intelligent self-care.”

Mr Dib also agrees that agencies can do more: “Considering the need to reinforce self-care in the Brazilian culture, the evolution of self-care practices in educational institutions and throughout media and educational campaigns is deemed as relevant.”

In China, Mr Bai explains that the government is currently developing self-care by establishing “a guiding ideology for improving the health of the whole population through a sound health education system.” And in recent years, China Health Education Institution (established by the National Health Commission) “has issued 66 regulations on the health of Chinese citizens and the development of disease prevention and control systems, which reflect the government’s emphasis on self-care.”

Additionally, in 2019 the Ministry of Education launched the “Healthy Teachers and Students, Healthy China” initiative. This requires health education to be integrated into all aspects of school education and teaching, with a focus on the whole life cycle of teachers and students and the whole process of health, thereby deepening school health education reform.

# Self-care approaches in the BRICS

## OTC medicines

BRICS countries' approach to OTC medicine access differs. To an extent, this affects the ability of populations to self-medicate. To demonstrate, the following is an overview of OTC systems and regulatory challenges in select BRICS markets:

### India

Consumer industry surveys found that 52% of India's population self-medicated with OTC medicines in 2015, up from 23% in 2006.<sup>371</sup> Despite this rise, India has been criticised by the pharmaceutical industry for not yet having a legal and policy framework to either support or regulate the marketing and promotion of OTC drugs, or establishing a clear pathway for OTC switches.<sup>372</sup>

Notably, the term OTC has no lawful acknowledgement or definition in India, neither in the Drugs and Cosmetics Act, 1940 – which governs all products classified as drugs – nor the Drugs and Cosmetics Rules, 1945. Instead, the acts provide a series of schedules that determine regulatory status. For example, drugs under Schedule H, H1 and X cannot be sold without a doctor's prescription. Theoretically, by default, nearly everything else is considered non-prescription and freely available OTC, although the law does not explicitly say this, the industry argues.<sup>373</sup>

According to Dr Reddy, non-prescription drugs are only legally available at pharmacies, not general stores. Unfortunately, he adds, while this legal requirement is strict, in practice there is a great deal of laxity.

Dr Reddy says that price control has also become a major part of India's health policy. "In 2014, 55 million Indians were pushed into poverty because of unaffordable healthcare expenditure. Out of that 55 million, 38 million were pushed into poverty because of expenditures on medicines... The policy [started in 2017] is to ensure that in public facilities all essential drugs will be provided free of cost."

### China

Traditional Chinese Medicines (TCM) and OTC medicines are both important parts of China's pharmaceutical market.<sup>375</sup> A 2016 study of community health centres (CHCs) – major providers of primary care services in China – found that 37% had used OTC Chinese herbal medicines (CHMs) in the past year and a majority of respondents found them effective. Furthermore, OTC CHMs were more popular among those who needed to pay out-of-pocket for CHC services.<sup>376,377</sup>

OTC medicines have been increasingly popular in China in the last two decades due to increased costs of medical services, an ageing population, a lack of health insurance coverage and the poor quality of healthcare systems at the community level.<sup>378,379,380</sup> The most popular medicines are for colds, coughs and allergies; lifestyle regulation (sedatives, contraceptives, smoking cessation, diet drugs, etc); and vitamins, minerals and supplements.<sup>381</sup>

## SELF-CARE DAY IN CHINA



In 2014, under the driving force of Dr Guo Zhenyu from the China Non-prescription Medicines Association, 'International Self-Care Day' was proposed by the World Self-Medication Industry, requiring activities to be carried out on July 24th each year to deliver the concept of 'national self-care'.



In 2014, 55 million Indians were pushed into poverty because of unaffordable healthcare expenditure. Out of that 55 million, 38 million were pushed into poverty because of expenditures on medicines... The policy [started in 2017] is to ensure that in public facilities all essential drugs will be provided free of cost.

**K Srinath Reddy**

president, Public Health Foundation of India (PHFI), India

As with prescription drugs, OTC drugs are regulated by the National Medical Products Administration (NMPA, formerly known as the China Food and Drug Administration). Medicines are divided into three classes: prescription drugs and OTC drugs, which are further split into class A drugs and required to be sold in pharmacies, and class B drugs, which do not have this requirement (general sales).<sup>382</sup>

Drug registration in China has historically been complex, known for onerous rules that took years for approval.<sup>383</sup> But by 2018 *The Economist* reported that China had successfully “introduced fast-track review for drugs for unmet medical needs, ditched the requirement to perform clinical trials with Chinese patients in state-run Chinese labs and relaxed rules that obliged many firms to invest in local factories.”<sup>384</sup>

The “drug classification management system and the related laws and regulations are not yet perfect,” agrees Mr Bai. Although the China Non-prescription Medicines Association is working with industry to institute reform, “the main challenge is that regulatory revision takes a while.”

Still the scope for using OTC drugs to self-medicate continues to expand worldwide, explains Mr Bai, and China is working to keep pace. “At present, there are 5,012 OTC drugs in China, accounting for one-third of the National Essential Medicine List. This fully shows the important role OTC drugs play in basic healthcare and the implementation of a healthy China strategy. Supporting the innovation of OTC drugs, increasing OTC varieties, dosage forms, taste, indications, and better meeting the different choices and needs of the public for self-medication will definitely help improve self-care capability in Chinese society and improve public health.”

### South Africa

Self-medication with OTC medicine is on the rise in South Africa, a trend often attributed to both increased education spurred on by internet access, and by low income levels that make doctor visits and time off work unaffordable, according to research by an industry group, Health Products Association of South Africa.<sup>385</sup> And, according to a 2013 study from South Africa, more highly educated parents said they preferred using OTC medicines for their child’s symptom relief whereas parents with a low education background preferred traditional medicines.<sup>386</sup>

South Africa has three tiers of medication – general sales OTC, pharmacy-only and prescription-only.<sup>387</sup> The South African Health Products Regulatory Authority has regulatory oversight of medicines and medical devices but its success has been limited to date, marked by under-resourcing and a growing backlog of applications.<sup>388,389</sup> It is hoped that, in time, new authority and leadership will help re-engineer strategies and processes to enhance the regulatory landscape.<sup>390</sup>

### Traditional medicines

Policymakers need to be aware that traditional medicines play an important role in how BRICS populations self-care.<sup>391</sup>

A 2016 study found that 11.7% of Indians reported that their most frequent source of care in the prior three years was traditional medicine. By contrast, less than 3% reported traditional medicine as their most frequent source of care in China, Russia and South Africa. Notably, the incidence of self-caring with traditional medicine was highest among poorer, less educated and rural participants.<sup>392</sup>

“Traditional medicine has been used for thousands of years in China,” explains Mr Bai. “To this day, many people still regard Chinese medicine as the number one choice when seeing the doctor, or a combination of both Chinese and Western medicine for diagnosis.”

Although there are significant challenges in guaranteeing the safety of traditional medicines and how they may interact with other medicines, patients often develop treatment plans that intertwine their modern and traditional options, according to studies.<sup>393</sup>

Doctors may also operate between expert and traditional medicine. According to one Russian report, doctors who have an additional specialty in a traditional medicine may work within a public medical institution while privately cultivating a patient base for their side-practice in traditional healing.<sup>394</sup>



Supporting the innovation of OTC drugs, increasing OTC varieties, dosage forms, taste, indications, and better meeting the different choices and needs of the public for self-medication will definitely help improve self-care capability in Chinese society and improve public health.

### Huiliang Bai

council member,  
International Self-Care Foundation (ISF), China

# Self-care approaches in the BRICS

And in China, traditional medicine is institutionalised, protected by law and officially promoted. According to official figures, at the end of 2015 there were 452,000 practitioners and assistant practitioners of TCM, 3,966 TCM hospitals across the country, and 42,528 TCM clinics. Altogether, there were 910 million visits that year to TCM services across the country.<sup>395</sup>

“Due to the increasing use of traditional medicine, government administrations place great importance on the monitoring of adverse reactions to drugs, including traditional medicines. It is a requirement for doctors who use traditional medicine to understand the theories of Chinese medicine,” explains Mr Bai. “They must also pay close attention to the issue of interaction between traditional and modern medicine, carry out research and improve monitoring.”

## The role of technology in self-care

### Digital apps

Forbes recently wrote that “Nowhere is this tension between technology’s promise and its unfulfilled potential more obvious than in China’s healthcare economy.”<sup>398</sup> The potential for the population to use technology to become more engaged and empowered in their health, the article argues, is diminished by the shortfalls of the public health system. Particularly by underfunding, under-staffing and gaps in the continuum of care. “In an environment where most public hospital physicians spend around five minutes with their patients on average, it is hard to see how technology can help them be more efficient,” the author writes, adding that “It is hard to see why Chinese families would stop doing what they already do, namely flock to a public hospital when they need to see a doctor.”

These issues may be recognisable in all BRICS nations. Nonetheless, the push to bring digital apps and devices to market continues. The global mobile health app market is expected to reach US\$102.35bn by 2023, according to some estimates.<sup>399</sup> While North America is dominating the space due to increasing healthcare awareness of chronic disease management, the Asia-Pacific region is expected to show high growth over the next five years because of China and India. Other key factors aiding the growth of these products in emerging countries are a large pool of patients and an increase in government funding.<sup>400</sup>

In the short term, success may mostly be focused around the numerous apps and devices tailored for long-term chronic disease management, such as diabetes and hypertension.<sup>401,402</sup> For example, in China, disease-specific phone apps were among the most commonly downloaded health apps, according to one report.<sup>403</sup> The study details that the most common diseases were diabetes, hypertension, liver disease and infertility, and that for diabetes, the apps were focused on record keeping and patient education.

According to Dr Reddy, personal devices like wearable watches and Fitbits are becoming more popular in India, particularly among urban, educated populations able to afford them. However, “a vast majority are still distant from some of those devices...On the other hand, a mobile phone is a very important instrument, and apps and information that can be transferred in terms of health literacy are already making a big impact. And they will be one of the major channels in the future for enhancing health literacy to the level of promoting good self-care,” he adds.

Regulation of medical devices falls to government health agencies. In Russia, the authority responsible for applying and enforcing regulations is the Federal Service on Surveillance in Healthcare,<sup>404</sup> in China, the NMPA has oversight of medical devices, and in Brazil, ANVISA. In each nation, respective agencies have introduced changes to the oversight of medical apps and devices, and each continues to develop the legislature landscape for devices.<sup>405,406,407,408</sup>

## CHINA’S EMBRACE OF TRADITIONAL MEDICINE



**“Traditional Chinese medicine emphasises one’s overall health status and individualisation and stresses the treatment of disease. It is a unique health service resource in China and is loved by the masses. Faced with the constant impact of modern medicine, Chinese medicine has not lost its market. The curative effect of traditional Chinese medicine on many diseases has become the basis for the efficacy of its existence.”**

**Huiliang Bai, council member, International Self-Care Foundation (ISF), China.**





#### TRADITIONAL AND MODERN MEDICINE, SIDE BY SIDE



In order to promote traditional Chinese medicine, in 2016 the National People's Congress enacted the 'Chinese Medicine Law of the People's Republic of China'.<sup>396,397</sup> While encouraging traditional Chinese medicine, the government insists that traditional Chinese medicine and modern medicine are equally important and that they complement each other.

**Source:** Interview with Mr Bai, council member of the International Self-Care Foundation (ISF), China

# Self-care approaches in the BRICS



I believe self-care is one of the most important elements of any good health management. It respects the individuality and autonomy of the patient. It's much more respectful of the patient and it recognises the patient as a participating partner in the whole process.

In a healthcare system like India, which is under great strain because of a very high level of demand and less supply of health professional services, engaging self-care as an important component is only going to improve the health outcomes and ensure that there are better returns on the economic investment in our health system. Ultimately, I believe that in terms of primary healthcare, it's going to be one of the game changers. I think that's the direction in which we ought to go, and I hope that India will move in that direction.

**Dr K Srinath Reddy**

president, Public Health Foundation of India (PHFI), India

"China's medical device and medical application-related regulations are at the stage of continuous development," explains Mr Bai.

"Traditional management methods are encountering real problems such as market admission, evaluation and guidance." He also points out that many health app developers do not have a medical health background. Some of the app Q&A information is copied from search engines, and credibility is very low; the disseminated health content also lacks scientific basis and accuracy, he thinks.

**E-pharmacies**

As seen in Europe and the US, regulators in BRICS are seeing an expanding e-pharmacy market, and are overwhelmed by efforts to regulate and verify the legitimacy of its many actors.

According to a 2016 report by Deloitte, China's online sales of pharmaceuticals account for only a tiny fraction of total sales.<sup>409</sup> However, with easing government policy, the report forecasts significant growth. In fact, in March 2018 the NMPA announced that around 991 new companies obtained the Internet Medicine Trading Service Qualification.<sup>410</sup>

Regulatory shortcomings have also been noticed: a 2017 Russian Pharmaceutical Market Trends report by Deloitte found regulation for online sales for OTC and prescription medicine to be one of the top areas requiring better government regulation.<sup>411</sup>

In China, the supervision and control of internet drug trading services is difficult, agrees Mr Bai. “The system of accountability is less than perfect, and regulatory authority approval is very cautious.” In response, in 2018 the China Food and Drug Administration issued a document that requested unified monitoring of the entire network, using information-based means to improve supervision efficiency, implement real-time monitoring and ensure the quality and safety of online drug purchases. “Software has already been commissioned for this work,” he says.

Meanwhile, in India, e-pharmacies were nationally outlawed in 2018 due to challenges in verifying the nature of a prescription.<sup>412</sup> Before the court decision to shut them down, e-pharmacies accounted for 1% of the retail market for pharmaceuticals.<sup>413</sup>

“It’s a fairly recent phenomenon, and there’s still a bit of controversy going on about it. Some of the groups are demanding that it should be restored, but at the moment the legal position is that internet sale of medicines is prohibited,” explains Dr Reddy.

## PREVENTING SEXUALLY TRANSMITTED DISEASES IN CHINA



China is trying to stem its epidemic of sexually transmitted infections (STIs) including HIV/AIDS, syphilis, chlamydia and gonorrhoea, particularly among men who have sex with men (MSM).<sup>414,415,416</sup> Unfortunately, in countries like China, stigma around STIs, late diagnosis, incomplete care and few targeted prevention programmes remain barriers to effective prevention and management.<sup>417</sup>

Self-care initiatives, such as self-testing for STIs, particularly HIV/AIDS, holds great promise for high-risk populations who do not have ready access to clinical services. For example, about 220 HIV self-test kits were sold per hour in 2017 by a single online pharmaceutical store in China, with particularly high demand from MSM populations<sup>418</sup> – a testament to e-commerce’s ability to improve uptake among high-risk communities.

However, access to physicians trained in STI diagnosis, prevention, treatment and behavioural counselling may be one of the most significant factors in stemming infection rates, according to a *Lancet* study.<sup>419</sup> The study concludes that because physicians act as gatekeepers to appropriate treatment, their ability to efficiently conduct a diagnostic interview and impart STI self-care education during brief patient consultations can have a substantial impact on existing and future infection rates. Nationwide implementation of physician training would require significant institutional and political commitment.

# Conclusion: Room to improve

Self-care has great potential to improve health outcomes for people and support savings for stretched healthcare budgets. And for policymakers, there is still a huge opportunity to recognise self-care as an important tool and make it a larger foundation of healthcare systems.

But there will not be progress unless policymakers take action. Self-care is not a magic bullet, nor is it self-sustaining. Stakeholders have to commit to building an environment where patients and HCPs alike are empowered and engaged.

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## Position self-care as an integral part of healthcare policy

Countries still have room to prioritise self-care in their healthcare policies. This encompasses prevention and health promotion, as well as supporting people to better self-manage conditions, including those that are chronic and/or self-limiting in nature. This can be achieved through better public health policies and improved education and health literacy so people can make informed decisions about health-seeking behaviour. Already some countries are leading the way. For example, the UK has seen a significant number of organisations participate in a European Self Care Week. The UK has also started to include self-care advice for patients in clinical guidelines for the management of migraine, for example.

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## Support research for evidence-based policies

Countries need to better understand their populations' relationship with self-care. This includes dependence on formal services for self-treatable conditions, when and why people have not fully engaged with self-care, health literacy levels, engagement by medical professionals in patients' self-management practices and patient awareness of supplemental services such as those provided by pharmacists and patient groups. More research on what resources are being wasted, and what further socioeconomic benefits self-care can bring, will all help to focus policy approaches to care.

Much of the existing research on self-care comes from North America and Europe, but even in these regions there are large gaps around self-care models, tools and behaviours that would help policymakers in drafting tailored, targeted solutions. Some Asia-Pacific economies, such as Taiwan and Australia, are building self-care research centres for the purpose of developing a stronger strategy. It is an approach from which other countries can benefit.

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## Train HCPs to empower patients

Studies across the globe have made it clear that patients are willing to manage their own care and can greatly benefit from professional assistance and support. Unfortunately, most HCPs are not taught fully how to best support self-managing patients. This can be better addressed by adding self-management training programmes in the curricula at higher education institutions teaching HCPs and through continuing professional development as part of supplemental on-the-job training.

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## Engage in pilot programmes

A variety of case studies demonstrate the benefits of empowering groups of chronic care patients, such as those with asthma, diabetes and renal failure, to manage elements of their own care. The results are strong health outcomes, higher quality of life for patients and less demand on services. Such studies and pilot programmes, which typically target small groups, should be reviewed for their potential for national adoption.

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## Empower pharmacists

Pharmacists are an underutilised resource in helping populations to self-care. Public awareness campaigns can help draw public attention to services and expertise they provide in local pharmacies, and emphasise when they are a more appropriate resource than physicians and emergency services. Additionally, healthcare systems should review how best to expand pharmacists' responsibilities.

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## Engage patient groups

Patient groups are passionately engaged in helping to improve healthcare systems when the provided care isn't appropriate. They are eager to work with policymakers and address patient safety gaps, and test self-care policies that can alleviate dependence on stressed health networks.<sup>420</sup>

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## Strike a balance for OTC medications

The ability to self-medicate is an important factor in self-care. The availability of OTC medicines can lessen reliance on prescription medicines, especially for minor ailments, and increase consumer choice. Regulators and policy frameworks should strike a balance between improving access to innovative self-care medications on the one hand, and public health considerations, including consumer safety, quality and efficacy, on the other hand.

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## Manage benefits and risks of new technology

Regulators will also need to seek a balance in improving access to innovative, effective self-care technologies, including apps and devices, while safeguarding consumers. New digital solutions are already ushering in a new wave of self-care opportunities. It is the responsibility of health regulators to ensure that populations can use the available tools effectively and are receiving reliable, trustworthy information in return. Efficient regulatory systems to manage the growth of medical devices and apps will become more important as this space develops and we learn more about benefits and risks.

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## Be realistic, and plan for the long term

Although self-care can reduce costs and increase patient outcomes, these are results that come from a well-planned long-term strategy. To view self-care only as a budget-saving tool will disappoint. Results will not show overnight and success requires energy, time, investment and dedication.

# Case study by RB

## Contraceptives – the switch to OTC

RB fully supports innovative ‘switch’ solutions that help consumers put health in their own hands. Using Emergency hormonal contraception (EC) as an example, once a prescription-only medication, it has been predominantly reclassified as an over-the-counter (OTC) medicine across the globe, allowing women to address their risk of unwanted pregnancy without consulting a doctor.

Global EC reclassification – the ‘switch’ to OTC status – largely took place in the early 2000s following debates around safety and ethics. Ultimately, most regulators found that EC met the criteria for such a switch, acknowledging patients’ ability to self-treat, self-diagnose and administer safely; the drugs were also effective when self-administered, and carried labels that were easily understood.<sup>421</sup>

The main forms of EC, ulipristal acetate (UPA; sold under the brand name Ella) and levonorgestrel (LNG; sold under the brand name Plan B), and their respective generics work by inhibiting or delaying ovulation. To work effectively, EC must be taken as soon as possible following unprotected sex. In this regard, timely access has been significantly improved by the switch to OTC access.

According to one study, the proportion of pharmacies in US cities that did not have LNG in stock on a 24-hour basis dropped from 22% to 8% in the year after the drug was reclassified as an OTC medicine in 2006. And a drop in Monday prescription-only sales was also reported, suggesting that more women were able to obtain the medicine in a timelier manner during the weekend, rather than having to wait for their local doctors surgery to reopen.<sup>422</sup>

“Without a shadow of doubt, the switch improved women’s access,” says Clare Murphy, Director of External Affairs, British Pregnancy Advisory Service. “It means women can take it quicker. It means they don’t have to have an appointment with a doctor or even the sexual health clinic. It means they’re not wasting a doctor’s time, and they’re not wasting their own time.”

Additionally, the change to OTC status has been shown to alleviate demands on emergency healthcare services. For example, in the year after the EC switch in the US occurred in 2006, emergency department visits for EC dropped 95%. As OTC awareness grew, US emergency department visits for EC dropped from 15,039 in 2007 to just 685 in 2014. Healthcare costs associated with such visits also decreased, from US\$6.2m in 2006 to US\$0.7m in 2014.<sup>423</sup>

# 96% drop

of visits to emergency departments after the EC switch in the US occurred in 2006.

## An underutilised resource

Perhaps surprisingly, although several studies show that OTC access to emergency contraception has increased utilisation, it has shown little to no effect on national rates of unwanted pregnancy.<sup>424,425,426,427</sup>

In fact, women who abort unwanted pregnancies are significantly more likely to have unsuccessfully used emergency contraception.<sup>428,429</sup> And among those that did not use EC after unprotected sex, studies found the cost of EC to be a factor, alongside poor knowledge about EC safety, privacy and efficacy.<sup>430,431,432,433</sup>

“EC is not a silver bullet for unwanted pregnancies, but it’s a massively underutilised resource,” says Ms Murphy. She argues that the availability of contraceptives is insufficient to tackle unwanted pregnancies alone. To achieve further progress, she says that policymakers and healthcare systems can do more to present women with the options available to them, and to better address persisting educational, cultural and institutional issues around EC.

“We have a safe product that gives women an important second chance, but we’ve basically made women feel they shouldn’t use it. We have wrapped it up in stigma and shame. And then surprisingly enough, they then don’t use it when they need it,” she says. “We need to do more about making women feel that this is a normal product.”

She adds that the issue may also be compounded by the intermediate step of pharmacist involvement in the behind-the-counter subcategory of OTC. During consultations pharmacists have an important opportunity to offer women advice on sexual health, condom use and to discuss other contraceptive methods. But as Ms Murphy argues, although policymakers and pharmacists may see women who had unprotected sex as ripe for intervention, women may feel it is not the time or the place to have that discussion. The consultation should be optional, she says, available for those women who want further information but not a mandatory requirement for access.

## Daily contraception switch

On the heels of the EC switch, drug makers and regulators now face growing pressure to consider an OTC switch for daily contraception pills (OCPs).<sup>434</sup>

Notably, a 2019 study by the World Health Organisation (WHO) of OTC availability of OCPs concludes with a strong recommendation that OCPs should be made available without prescription – either off the shelf or behind the counter – which could in turn increase use and reduce unintended pregnancies.<sup>435</sup> According to the report, the Guideline Development Group “agreed that the benefits outweighed the harm”. Furthermore, the WHO found that OTC availability is not only cost-saving and feasible in nearly every country, but that it “is likely to increase access and reduce discrimination (supporting human rights), especially among adolescent girls and young women and sexual and gender minorities.”

It would be a promising direction for daily contraception to switch to OTC availability, agrees Ms Murphy. “There is a real public health and moral impetus on us to improve women’s access to contraceptive services. And I definitely think in some context that will be through reclassification and pharmacy access.”

As the WHO and other studies are quick to point out, initial research on the safety and efficacy of a switch to OTC availability of daily contraception is promising. As with EC, studies show that women are prone to safe adherence and show little risk of misuse of daily birth control. Notably, a 2006 report showed that women’s self-evaluation regarding whether or not they should take the daily pill matched those of doctors about 90% of the time – and 10% didn’t match mostly because the women erred on the side of caution and felt that they should take the pill.<sup>436</sup>

There is also convincing evidence that reclassifying prescription birth control pills as OTC increases their continuous use.<sup>437</sup> And, as with EC, the OTC switch for daily contraception can also save women and healthcare systems resources in the long term, as well as offering women convenience, choice and privacy.

For now, it is unclear if OTC availability of daily contraception will encounter the same cultural and health literacy barriers as EC, but it falls to policymakers and healthcare providers to ensure that women are empowered to self-care in a safe and efficient manner; removing barriers to EC and daily contraception is a good place to start.

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