

Science-Led Self-Care: Principles for Best Practice

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Note to readers

Self-care is a growing part of our consciousness and daily lives. There are many reasons for this, including the rise in digital technology, enabling people to make more informed decisions around their own health; increased strain and costs facing healthcare systems worldwide; and new innovative over-the-counter (OTC) products, among others.

We believe that ultimately, self-care is about empowering the consumer to look after their health and wellbeing, and making healthcare understandable and accessible to all. Enabling consumers to find their own healthcare solutions, from prevention to treatment, offers the potential to relieve the growing pressure on health systems worldwide – not only by reducing clinical footfall, but also by supporting consumers to maintain their health and reduce the risk of future illness and frailty. And in some cases, particularly in low and middle-income populations, it might be their only access to meaningful health solutions.

With an <u>ageing world population</u>, the focus of healthcare is shifting to preventive strategies to maintain people's health and wellbeing into old age. This is increasingly important as the number of patients with chronic and multi-faceted disorders grows with age (<u>Barnett K, et al.,</u> <u>Lancet 2012</u>), intensifying the demand for general practitioner (GP) consultations and time. Indeed, according to our own recent research, 'healthy ageing' is a topic at the forefront of consumers' minds – second only to COVID-19.

Further, the information base for science-led self-care is growing fast. Digital biomarkers are able to provide more information than ever to help contribute to overall good health, and combined with advances in biology and computing (including data science and artificial intelligence [AI]), are driving what has been termed the <u>Bio-Revolution</u> – with accelerated innovation significantly improving health and wellness, including preventative solutions as well as precision health products.

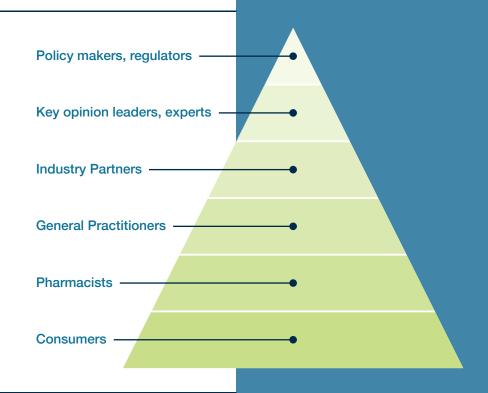
Given reduced touchpoints with healthcare professionals (HCPs), thanks in part to the COVID-19 pandemic, and an increase in the availability of digital technologies to track and monitor our wellbeing, consumers are becoming increasingly interested in maintaining and managing their own health. While the consumer is typically the end user of self-care products, however, they aren't the only stakeholder in the self-care industry. The different audiences in the self-care industry and in healthcare as a whole can be described as a healthcare pyramid.





THE HEALTHCARE PYRAMID

For Bayer Consumer Health, the healthcare pyramid consists of consumers (the largest group, at the base), moving up to pharmacists and general practitioners (GPs), through industry partners, then expert prescribers and key opinion leaders (KOLs), to regulators and policy makers. The different stakeholders in the pyramid all benefit from credible self-care products rooted in science - including the pharmacist recommending a solution to the consumer: GPs who can benefit from reduced administration and clinical burden if they are able to recommend credible, proven non-prescription products; and KOLs, experts and industry, so they can continue to drive areas of investigation and discovery.



What is 'self-care'?

The <u>World Health Organization (WHO</u>) defines self-care as 'the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health worker.'

A web search for self-care brings up over 3.5 billion hits. However, the results are dominated by discussions of the importance of 'me-time', stress reduction, and eating well – focusing on only a small component of the broader WHO definition. Although self-care has become synonymous with the health and wellness industry, many products promoted for self-care are not based in evidence or grounded in deep science, and the term 'self-care' is itself not focused on the prevention of disease – on keeping and staying healthy.

Everyone in the self-care industry thinks it, though no-one is prepared to say it: science-led self-care companies have been swept along with bubble baths and yoga, rather than emphasizing that self-care exists in a broad health care continuum. What's more, consumers think so too.

We think this is a topic worthy of deeper discussion, and believe self-care's accessibility for consumers is underpinned by two factors: available products, and credible information to make informed decisions on the right choices for their health. Consumers need to be empowered to know how to distinguish the products and practices that might be 'nice to have' from those that can be instrumental in protecting and promoting their own health. When you see people refer to self-care it's people going to get spa services or mani-pedis, or a certain type of yoga"

Consumer, US, BCH Consumer Survey 2021

Self-care doesn't fit with pain relievers, it's more to do with you, not so much to fight pains... many people take things they do not need... it needs technical guidance."

Consumer, Germany, BCH Consumer Survey 2021 Trust and transparency are arguably the self-care industry's biggest challenge – information and guidance are out there, but must be based on solid evidence, fact-checked and credible. The recent Global Self-Care Federation <u>Trust Audit</u> found that 74% of consumers trust the self-care industry, with this trust driven by product safety, efficacy, regulation and transparency. In contrast, stakeholders (such as medical organisations, policy makers and patient advocacy groups) are less trusting, with 21% saying they actively distrust the self-care industry, though in general they recognise the potential benefits of self-care to relieve the pressure on healthcare systems.

The self-care imperative

In today's world of access to nearly limitless information – and, increasingly, misinformation – helping consumers make this distinction becomes a moral imperative. We believe that trust and credibility, founded on transparent science, holds the key to helping consumers make this distinction. In this paper, we propose a series of five core principles that make up what we believe is the best science-led self-care. These principles combine to help meet the core needs of consumers who are looking to take more control over their personal health decisions. The following pages will detail these principles and how we apply them to our work within Bayer Consumer Health.

While these principles are core to how we operate at Bayer, we think the public need for credible, science-led self-care is so great that we propose these principles as a starting point for industry to get behind. We look forward to kicking off a robust discussion with industry peers, health and medical professionals, policy makers, and consumers about how these principles can continue to evolve and develop to contribute to a better health future for all.



David Evendon-Challis Global Executive Committee Member and Chief Scientific Officer, Bayer Consumer Health



Abbie Lennox Global Executive Committee Member & Global Chief Regulatory, Medical, Safety and Compliance Officer, Bayer Consumer Health



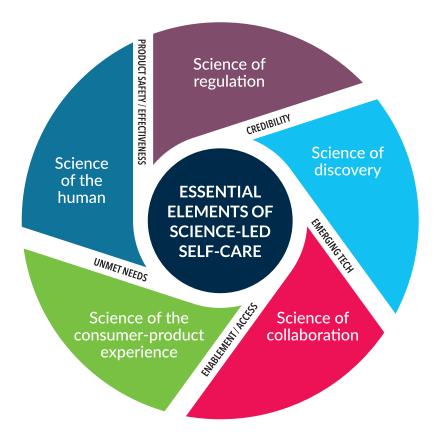
Section _

The scope and format of this paper

The aim of this paper is to lay out the five key principles, as seen by Bayer Consumer Health (BCH), of science-led self-care solutions. For each principle, we present the rationale we have to validate its position as a critical piece of science-led self-care, supported by proprietary research and analyses undertaken internally at BCH alongside external data (such as insights from HCPs and consumers). These data, along with illustrative product examples from our portfolio and experience developing innovative self care products at BCH, are summarised in each of the following chapters, along with key points and conclusions.

The conclusions are broadly applicable to all the levels of the healthcare pyramid illustrated above: in other words, to anyone with an interest in consumer health and wellbeing. As such, the paper is intended to be understood by a broad audience.

Read on to explore each principle of science-led self-care in turn, examining what it means and why we feel it's important.





Section

Overview of self-care

Self-care has become a broad term, used in some countries to refer to everything from treating illness with over-the-counter (OTC) medicines, through nutritional supplements, to massages and mindfulness, but it has an official definition focused very much on independent self-management of people's health:

The World Health Organization definition of self-care:

The ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health-care provider.

The Global Self-Care Federation (GSCF) represents associations and manufacturers in the self-care industry and recognises the WHO definition of self care. Together with the WHO, the GSCF works to achieve universal health coverage and promote healthier populations worldwide through the medium of science-based self-care. GSCF works closely with its members and relevant stakeholder groups to ensure evidence-based self care products and solutions are recognised as key contributors to health for individuals and systems worldwide.

Bayer Consumer Health (BCH), a division of Bayer AG comprising over 170 brands, is a proud member of the GSCF. We are continually striving to improve people's access to affordable health products, as well as information and education. We feel that science-led self-care is a critical enabler to a better life for billions of people around the world through everyday healthcare, and central to meeting our vision of <u>Health for all,</u> <u>hunger for none</u>.

What is the Self-Care Readiness Index?

Developed by the GSCF, the <u>Self-Care Readiness Index (SCRI)</u> is an advocacy-centred research initiative developed to help better understand, recognise and implement the enablers of self-care, as well as how to improve them. It is comprised of desk research, surveys and expert interviews in ten countries across the globe (with an additional 10 countries to be added in late 2022), incorporating at least one country in each of the WHO's regions: Africa, the Americas, South-East Asia, Europe, the Eastern Mediterranean, and the Western Pacific. As part of this research, four key enablers were identified that are needed to realise the full potential of self-care: *Support and adoption by stakeholders; Consumer and patient empowerment; Self-care health policy; and Regulatory environment.*

A key theme to emerge from research undertaken for the SCRI was that self-care is not a universally well understood concept, meaning different things in different cultures. This lack of a single universally accepted definition of self-care, and of its products and services, can ultimately



The World Health Organization definition of self-care: The ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health-care provider lead to missed opportunities in promoting self-care and thus benefiting from its population-level advantages. Further, the SCRI research observed that the information available to patients and consumers on self-care products and behaviours is not always accurate or helpful, with harmful misinformation widely available on the internet. Clearly, work is needed to support consumers to understand their health, and the available options for science-led self-care, more clearly.

As a science-led company, what does this definition of self-care mean to us?

We believe that companies like BCH have a responsibility to provide trustworthy, evidence-based solutions to the consumer's nonprescription healthcare needs, using our deep understanding of biology and consumer needs to deliver innovative products – and keeping on top of changing needs and paradigms.

Critically, self-care is about empowering the consumer to manage and protect their own health, supported by science-led solutions. Self-care-associated education can also increase people's focus on and understanding of wellness and prevention, keeping many more people healthy and decreasing their need to consume healthcare resources (e.g., doctor visits, hospitalisations, prescription medication). This can further help to reduce the burden on overstretched health systems.

What are the key challenges facing the self-care industry, now and in the near future?

The health and wellness industry is growing rapidly, reaching a global value of <u>\$4.9 billion in 2019</u>. It comprises beauty, mental wellness, personal care and fitness, as well as nutrition and weight management, healthcare maintenance and over-the-counter (OTC) medicines for the self-treatment of minor illnesses.

Self-care is by definition consumer-led, assuming the consumer understands their own health and wellness and, armed with the right knowledge, is empowered to maintain or supplement it. But we live in an era dominated by 'fake news' and variability in health literacy across different communities and geographies. The meteoric rise of social media has brought with it a flood of misinformation, making it challenging to sift truth from untruth. In this environment, how does the consumer know what and whom to trust?

What's wrong with bubble baths?

Of course, there's nothing wrong with bubble baths – taking time for yourself is important. However, there is an important distinction to be made between data-driven, active self-care, where the consumer is taking active steps to improve and maintain their health using tools supported by rigorous science, and the more passive approach of 'me-time'. The value of science-led innovation needs to be recognised – and in today's world of misinformation and rumour, rigorous testing and regulation has never been more important. Consumers need products they know they can trust. We believe that self-care means consumer access to innovative, evidence-based solutions to manage their own health, alongside empowering them through education about available self-care choices

There are concerns [from consumers] around the standard of evidence and the extent to which they back up marketing claims."

Regulator, GSCF Trust Audit

Section

Principles of science-led self-care

What are the essential principles of science-led self-care?

There are multiple factors that make up a science-led self-care product or service. At BCH, we have grouped these into five key principles, which we believe are the key principles that enable the discovery and delivery of a self-care product that is rooted in deep science:

- The Science of the Human
- The Science of Regulation
- The Science of Collaboration
- The Science of Discovery
- The Science of the Consumer-Product Experience

PRODUCT SAFETY / EFFECTIVENESS Science of regulation CREDIBILITY Science of Science discovery of the **ESSENTIAL** human **ELEMENTS OF** EMERGING IECH SCIENCE-LED SELF-CARE UNMET NEEDS the second secon Science of the Science of consumer-product collaboration experience

Key principles of the science of self-care

Each principle must be founded on research and insight, generating a deep understanding – whether that be an understanding of the medical need, the biological process addressed by the product or the human need of the consumer themselves. It's essential that a self-care product addresses the needs of the whole person, whether those needs are communicated by the consumer's voice, in feedback during our insights research, or by their body's biology. By understanding this, we can continue to develop self-care products that support people to not only get well, but stay well – to address symptoms of illness, but also to go beyond that. For reputable companies engaging in science-led self-care, these principles will already be a part of their process. These are what set science-led self-care products apart.

The following chapters outline our current thinking of what constitutes science-led self-care. However, we are aware that there are questions remaining – and we don't have all the answers. We have outlined what we believe are some of the key outstanding questions at the end of each chapter and the final part of this paper, but this is meant to start a conversation. We look forward to starting this conversation and continuing to find new solutions to the challenges facing science-led self-care.



Chapter 1 The Science of the Human

KEY POINTS

The development of self-care products should be rooted in a thorough understanding of human biology and credible medical insights, both to deliver a true medical benefit and to ensure products' safety.

The Science of the Human includes an understanding of unmet human needs, which the consumer themselves can recognise and respond to.

Clear and understandable communication around each self-care product is critical to support the consumer to make informed decisions about their health.

The needs of the body: Understanding human biology

A self-care product must always answer a genuine medical need: for BCH, the development of our self-care products is always grounded in a deep understanding of human biology. Medical insight is at the heart of BCH's innovation cycle – all our everyday self-care products have a robust evidence base that demonstrates their biological safety and effectiveness. And in many cases, this includes clinical trials.

Medical insight is particularly critical in light of the ageing population worldwide (<u>United Nations, 2019</u>): by 2050, 1 in 6 people will be over the age of 65, and people are living longer beyond 65 as well. Older people tend to have more disorders requiring medical care (<u>Barnett K, et al., Lancet 2012</u>), so this ageing trend is expected to increase the pressure on healthcare systems, making the role of self-care in relieving that pressure ever more important. Self-care can also help people to stay healthy as they age, with new scientific knowledge and technology potentially helping use to slow age-related decline in function. Studies are ongoing to examine the influence of lifestyle factors, such as nutrition, on the epigenetic changes – in other words, changes in how our genes work during our lifetime – that occur as we age (<u>Peng H, et al.</u> Aging (Albany NY) 2021; Fitzgerald KN, et al. Aging [Albany NY] 2021) and scientists worldwide, including at BCH, are working to find new solutions to help people to stay healthy for longer.

When underpinned by medical insight, self-care products can have a broad sociological impact. Opioid over-prescribing, misuse and dependence is a problem globally, but has been particularly prevalent in the US; dentists are among the top opioid prescribers in the country (Suda KJ, et al. Am J Prevent Med 2020), frequently offering patients opioids for relief from the pain of dental procedures. At BCH, we know that Aleve, an OTC pain-reliever, can offer pain relief in a range of situations, and we believed it could help reduce reliance on opioids.



I think we learn from medicine everywhere that it is, at its heart, a human endeavour, requiring good science but also a limitless curiosity and interest in your fellow human being."

Abraham Verghese

To test this hypothesis, we launched two clinical studies, which have shown that naproxen, the key active ingredient in Aleve, works to relieve the pain of dental procedures, including extractions. In fact, from the 3-hour mark in both studies, patients taking naproxen reported *reduced* pain compared with those taking paracetamol plus codeine, making Aleve a compelling, non addictive alternative for minor dental pain relief.

The needs of the consumer: The importance of human insight

The medical need should always be paired with consumer insight. If a self-care product addresses a problem the consumer doesn't know they have or doesn't know how to manage, it is not a product that helps them take more ownership of their own health. A key insight in recent years is the increasing concern of consumers about the health of their immune system – according to a <u>Neilsen study</u>, 70% of consumers are open to taking active steps, such as nutrition, to improve their health – even if they feel well. The COVID-19 pandemic has brought the importance of ongoing wellness and nutrition into the spotlight.

At BCH, we have responded to this by working on a new range of immune-boosting supplements, such as a newly launched Berocca vitamin supplement that included probiotic and herbal ingredients, to help consumers to meet these needs, supporting their physical barriers (such as the skin), cellular defences and antibody production. Through greater support for consumers' immune systems, we can help to meet these needs to support their daily health.

The nappy care ointment <u>Bepanthen</u> also serves to highlight the importance of understanding the consumer. Bepanthen, containing dexpanthenol, otherwise known as provitamin B5, has been used to soothe babies' skin and aid its natural recovery since 1944. Recently, consumers advised us that tattoo artists were recommending Bepanthen for tattoo aftercare. We recognised the unmet need for better solutions for tattoos – a form of wound – and conducted clinical studies on tattooed skin. As a result, we were able to launch a <u>new</u>, <u>targeted</u> range of A+D products for post-tattoo care, and guide people on how best to care for their tattoos so that they heal effectively.

The importance of clear communication

The medical needs addressed by a self-care product must be clearly and understandably communicated to the consumer, to support them to make informed decisions about their health. This is true for any product, but even more so if the product can address more than one medical issue.

The antihistamine, loratadine – the active ingredient in <u>Claritin</u> – was originally used by consumers to treat hayfever, and only hayfever. As part of our ongoing research into the area, BCH scientists understood that the hypersensitivity reaction triggered by the immune system in response to pollen allergens was the same as that triggered by other allergens, such as pet fur and dander (dead skin cells). Understanding the body's reaction to allergens meant Claritin's packaging could be updated to



show it could work for both outdoor seasonal, and indoor allergies. As a result, the packaging helps the consumer to understand that they need one product for all their allergy needs.

Communication must be appropriately targeted to its audience and underpinned by research. Cardiovascular disease affects us all, but there is a lack of representative data for women and Black Americans. BCH is undertaking detailed real-world research, due to report in 2022, on 15,000 consumers to better understand risk factors, what people in these populations take to help treat their disease (for example, aspirin) and what affects their compliance to these treatments. Once we have analysed these data, we aim to build them into targeted communications for these populations to support them to better understand their symptoms and how manage them.

BCH is committed to accurate and credible labelling of our products, including making use of advances in digitalisation and electronic labelling to support improved health literacy for consumers. Many of our brands openly share product origins, details of the supply chain and their ethics around sourcing in a clear, digestible way. For the German launch of a new offering from <u>lberogast</u>, BCH's herbal digestive health brand, we included an on-pack QR code which explained more about each of the herbs included in the product, including where they were grown and why our scientists choose them. On our products in Guatemala, QR codes support health education on smaller packs for lower-income consumers, where space for labelling is reduced – gaining approval for this approach from the local regulatory agency was a national first.

We believe that by understanding and acting on the needs of their own human biology, we can help consumers to take more control over their own health – critical to effective self-care.

Questions for the future

With the Science of the Human in mind, how can we best effect positive change in the self-care industry as a whole?

How will COVID-19 affect consumer lifestyles in the long term, and how does this change behaviours in relation to health and wellness? What impact could this have on the Science of the Human?

What role should digital tools play in deeping everyone's understanding of the Science of the Human and are there opportunities for cross-industry collaboration.



Chapter 2 The Science of Regulation

KEY POINTS

Independent regulation, to ensure safety and efficacy through transparent communication, accurate labelling and supported claims, is central to maintaining trust and credibility among consumers.

When regulatory systems and requirements are fit for purpose, they support greater access to self-care by enabling people to take more control over their own health.

Incorporating real-world evidence into the regulatory process, as well as improved global alignment, are critical to the global objective of improving access to everyday healthcare worldwide while ensuring safety and credibility.

Harmonisation of regulatory review across geographies, along with regulatory requirements that are proportionate to risk, are important to enable broader and more consistent access to science-led self-care.

The importance of robust regulation

Despite the speed at which the industry innovates, non-prescription everyday healthcare products developed by the consumer health industry are robustly regulated. Products are audited and/or reviewed by regulators prior to marketing to ensure they meet safety and efficacy standards, have good manufacturing practices and are labelled accurately. This is essential to ensure that products really do deliver on the claims they make.

As well as ensuring safety and efficacy, such regulation is a key driver of trust (<u>GSCF Trust Audit</u>) and the <u>GSCF Code of Ethics</u> demands, amongst other things, full cooperation with regulatory agencies around the world to ensure the health and well-being of consumers using self-care products. The GSCF Code of Ethics is something BCH has welcomed and is fully committed to.

The importance of credibility and transparency

Regulatory processes for self-care products demand a robust evidence base, and at BCH we work tirelessly to build our scientific knowledge and present evidence that demonstrates the safety and efficacy of all our products.

As part of the development of the <u>Elevit</u> range, a brand of nutritional products that support people trying to conceive and women who are pregnant or breastfeeding, our team published a randomized, controlled clinical trial investigating the role of multi-micronutrient supplementation for both maternal and foetal levels of docosahexaenoic acid (DHA) –



Product safety, efficacy, regulation and societal benefits are positive attributes of the self-care industry."

Global Self-Care Federation, Understanding Trust in Self-Care a nutrient that is key to development before and shortly after birth (<u>Massari M, et al. Nutrients 2020</u>). A separate clinical trial also identified the role of these supplements on levels of DHA in the breast milk of breastfeeding mothers (<u>Schaeffer E, et al. Nutrients 2020</u>). Before these trials were published, we were convinced that multi-micronutrient supplementation would be beneficial – but by running a rigorous clinical trial, we can be certain, and so can the regulators – and, importantly, our customers.

We believe our dedication to transparency inspires trust and credibility in our company as a whole, as well as in the products we develop. In line with this, Bayer has developed a robust <u>Transparency Policy</u>, and is fully committed to publicly disclose information about all its planned and ongoing clinical trials, which evaluate our consumer health products as well as our prescription medicines. Our new <u>Bayer Science Collaboration</u> <u>Explorer</u>, initially rolled out in Germany, helps us to share information on our contracts to undertake research with external collaborators, including universities and individuals.

Clinical trial results support the regulatory process and trial results are accessible to the public irrespective of whether the results are positive or negative. Recent clinical trials for BCH self-care products include a study of <u>Canesten Cream</u> for vaginal yeast infections, and a study of <u>Astepro</u><u>nasal spray</u> (recently approved for OTC use in the USA) to establish how quickly it starts relieving the symptoms of hay fever. The results of completed clinical trials, such as that comparing <u>fast-release aspirin to</u><u>the ordinary formulation</u>, are available on our <u>Clinical Trials webpage</u>.

Ensuring regulation continues to be fit for purpose

Innovation is the lifeblood of the self-care industry, and as knowledge and capabilities in the field of self-care evolve, it is important that regulations keep pace to ensure that consumers' needs can continue to be met. Regulation needs to help to meet the aims of self-care: to support people to take more control over their own everyday health and wellbeing. Regulatory requirements should also be in proportion to the risk presented by the product in question: overly strict regulation of products that pose a limited risk to public health can restrict muchneeded access for consumers, while proportionate regulation can also allow greater scrutiny to be directed towards products presenting greater risks to consumer health.

Thanks in part to the digital revolution, the availability of real-world data for self-care products from apps and smart devices has rocketed (<u>AESGP Position Paper, 2021</u>). Such data can provide critical insights, not only into product safety but also the effectiveness and outcomes of self-care products. Real-world insights could also be pivotal in supporting the transition of some medicines from prescription to non-prescription, making access to medicine easier for people around the world.

The switch of medicines from prescription to over-the-counter (OTC) approval highlights another issue for regulators to address: global alignment. A key differentiator affecting levels of trust in self-care across

Our regulatory decisions are impartial and based solely on the extensive evidence required for each product"

UK <u>Medicines and</u> Healthcare products Regulatory Agency (MHRA)



different regions, as well as the access of consumers to new products, is the rigour, application and use of regulation (<u>GSCF Trust Audit</u>), making greater alignment between regulations and regulators worldwide highly desirable. Products which have long been considered safe for OTC use in many countries are still limited to prescription by clinicians in others, and regulatory requirements and standards can also vary by region. Greater alignment worldwide will not only improve consumer and stakeholder trust, but also improve access to healthcare.

We are committed to working in partnership with regulators, maintaining our efforts to drive forward innovation transparently and ethically, while helping to find solutions and innovations on the regulatory side, where needed, to ensure regulatory practices continue to reflect the technological environment.

As a consumer health company, we develop products that address a medical need and are underpinned by customer insight; however, appropriate regulation is critical to validate these insights and ensure that companies demonstrate evidence to support the product functions as intended. Regulation and the scientific evidence it demands is the backbone of the processes we use to of gather insights and develop products, ensuring that we deliver self-care products that are rooted in science, and are safe and appropriate for the population as a whole.



Questions for the future

With the Science of Regulation in mind, how can we best effect positive change in the self-care industry as a whole?

What can be done to make the regulatory process more transparent, understandable and harmonised for consumers across the globe to help increase trust and uptake of self-care?

What challenges do regulators have in keeping pace with innovation, science, and new evidence and how can industry and other stakeholders help address them?

How will COVID-19 affect consumer lifestyles in the long term, and how does this change behaviours in relation to health and wellness? What impact could this have on the Science of Regulation?

Chapter 3 The Science of Collaboration

KEY POINTS

The best innovations come from great minds working together: diversity powers creativity and helps us to reduce risk.

At BCH, we have a strong network of external partners with varying areas of expertise to help us to keep finding new ways to support consumers' everyday health.

Carefully judged collaborations focused on win-win outcomes can help to improve access to self-care, making products available more widely and empowering more consumers to take charge of their health.

Diversity as a propellant

Good ideas can come from anywhere – and they often do. Diverse teams – bringing together different strengths, generating new ideas, accounting for different backgrounds and experiences, and reducing blind spots – serve as a propellant for innovation engines. According to an <u>assessment by Deloitte</u>, diversity of thinking is a wellspring of creativity, enhancing innovation by about 20 percent. It also enables groups to spot risks, reducing these by up to 30 percent.

Understanding the needs of the patient/consumer and healthcare professionals is key to ensure that we continue to support and expand access to the healthcare system, focusing on how we improve and promote global wellbeing. So before we innovate our pipeline of products and services, we work to understand people's needs through consumer insights, and to understand the body's needs through medical insights. The more diverse teams we bring together in collaboration, the better we can fulfil the promise of providing greater access to healthcare and improved wellbeing worldwide.

Collaborating to innovate

Despite our internal expertise and capabilities, we know the best innovations generally come from great minds working together, and we recognise the value of outside expertise to keep moving forward. For this reason, BCH has developed a strong and diverse network of external partners who can offer complementary skills and experience, enabling us to accelerate ongoing innovation and deliver novel self-care products that are differentiated by science and transform everyday health for consumers. Ultimately, this means bringing better products to those who need them – faster.



"

Alone we can do so little; together we can do so much." *Helen Keller*



We created our Partner with Us program designed to increase our partnerships. Through this initiative, we are actively engaging in venues with partners in areas where we think outside expertise can compliment our own, but also to showcase the value Bayer can bring to partnerships through things like our innovation engine and global footprint. Through Partner with Us, we are taking a proactive approach to ensuring partners know that we are open for business with them in search of win-win collaborations.

Another area where we are looking to partner is through LEAPS by Bayer, the impact investment unit of Bayer AG. This group which acts somewhat independently of our business units is focsed on overcoming the biggest challenges facing humanity today by building new companies and investing in paradigm-shifting scientific advances across the spectrum of health and agriculture. This group focuses on high-risk, high-return ventures on the cutting edge of innovation and a number of these have the potential to lead to significant improvements in the self-care field. LEAPS by Bayer has already invested in a number of companies making great strides forward in consumer health; the benefits they could bring to consumers are outlined in the next chapter.

But collaborating well is a science in and of itself. To begin with, it's important to identify the right partners. We actively seek out teams who have new ideas, capabilities, insights and strengths that we might not have, taking a rigorous and data-led approach to reviewing and identifying the right people to collaborate with. We also host competitions, bringing together the brightest minds in consumer health to tackle the toughest challenges facing the self-care industry today.

Once we have identified a partner, we are committed to working closely with them to ensure we deliver on the vision that brought us together. For our partners, this commitment means access to much-needed investment and technical capacity, as well as market access, brand awareness and a deep understanding and experience of the regulatory environment. Most importantly, it means knowing they are working with a science-led and trusted global company that can help them grow and reach more people.

Collaborating to educate

Carefully judged collaborations can also allow us to boost health literacy and empower more consumers to take charge of their health, as well as working to maintain standards worldwide. In India, our partnership with the <u>Federation of Indian Chambers of Commerce and Industry (FICCI)</u> helps us to promote responsible self-care, something that is particularly critical in a region predicted to have the world's largest workforce by 2027. India's first Self-Care Council aims to navigate and address pressing topics and misconceptions about health and sustainability, while boosting health literacy across the country.

Collaboration, when rooted in complementary medical insights, skills and experience, will help us to provide new solutions to consumers' changing needs, and drive continued growth in the self-care industry.



Questions for the future

With the Science of Collaboration in mind, how can we best effect positive change in the self-care industry as a whole?

How can collaboration and partnerships impact areas like sustainability and improving access to self-care in under-served populations?

What impediments exist for partners like small start-ups to work with larger companies?

How can we grow partnerships with non-commercial organizations like universities or non-profits to expand science-led self-care?

How will COVID-19 affect consumer lifestyles in the long term, and how does this change behaviours in relation to health and wellness? What impact could this have on the Science of Collaboration?

Chapter 4 The Science of Discovery

KEY POINTS

Rigorous research and development, founded on scientific principles and an understanding of consumers' unmet needs, is central to advancing self-care products and services.

The rise of digital and wearable technology has enabled consumers to share greater insights about their daily health, opening the way to novel solutions.

Controlled clinical studies offer a robust way to assess whether a product actually offers a benefit, and should be a common feature of developing credible self-care products.

The role of scientific investigation in the field of self-care

Innovative science is key to advancing self-care products and services, as much as it is for prescription-only medicines. This is exemplified by the fact that research and development (R&D) for consumer healthcare in many cases sits alongside that for pharmaceuticals. The use of rigorous scientific evidence is foundational to the ethical development and promotion of self-care products – and the latest science can help unlock new approaches to meet consumer needs. At BCH, we strive to harness emerging science across our global network of research and development sites to identify new ways to meet the health and wellness needs of our customers: our knowledge and available products are continually evolving.

Progress and innovation based on solid scientific data and investigation are a hallmark of science-led self-care. But – as always – in order to identify the best solutions for people's needs, we are also reliant on consumer insights. Our local teams use rigorous market research and data analytics to identify and better understand what people need right now, as well as to predict what they are likely to need in the future.

Emerging science – the role of collaborations

Collaborative partnerships, as outlined in the previous chapter, are often a driving force behind innovation and identification of new products and services. At BCH, we are proud of the partnerships we have made, which are enabling us to extend the boundaries of the possible within self-care.

We are only beginning to discover the ability of the microbiome in the gut and on skin to influence health. As such, we have targeted this as a focus area of our basic research efforts. Our joint development



"Now, here, you see, it takes all the running you can do, to keep in the same place. If you want to get somewhere else, you must run at least twice as fast as that!"

The Red Queen, Through the Looking Glass (Lewis Carroll) partnership with <u>Azitra</u> promises to give rise to new, natural skincare products built on deep medical insight. Azitra's technology aims to harness the skin's own microbiome, or 'skin friendly' bacteria, to develop new natural skincare products for eczema-prone and sensitive skin, as well as potentially even for skin diseases such as psoriasis. This innovative approach, founded on cutting-edge medical insights, is expected to offer significant benefits for improved skin health and appearance, and may help to stop the vicious cycle of eczema flare-ups.

We are also working with Edifice, who harness a scientific understanding of inflammation to improve health in ageing as well as inflammatory and immune health. Edifice has developed the first ever method of assessing systemic chronic inflammation, the root cause of multiple chronic age-related diseases, and uncovering our true biological age in the process. Once a person's biological age is known, supplements can be highly targeted to improve inflammatory health and support us to stay healthy as we age. Building on collaborative science, self-care is thus moving away from guessing what will help support our long-term health and towards building tailored solutions based on proven scientific understanding.

Harnessing the digital revolution to improve self-care offerings and outcomes

Today, in the Information Age, digital technology is further accelerating scientific discoveries, including in the self-care field. The increasing popularity of digital trackers and smartphone applications allows consumers to share insights about their daily health – potentially enabling us to tailor solutions to individual needs. Vast quantities of data can be gathered in this way, but the next challenge is analysing the information and understanding what it means. Luckily, new capabilities in artificial intelligence (AI), automation and data analytics support us to work through this huge amount of data and identify completely novel approaches to improve health.

The synergism between digitisation and the life sciences has been termed the <u>Bio-Revolution</u>, and has the potential to help us to tackle global challenges – from climate change to global pandemics. It has been estimated that around <u>45% of the current global burden of disease</u> could be addressed using science that we already have available to us today.

Building on the Bio-Revolution and digital enablers, self-care is moving beyond single remedies for individual issues to creating health and wellness ecosystems. Cardiovascular disease is the leading cause of death worldwide, and we want to change this. Working with Huma. Therapeutics, we launched a six-week study with 500 sufferers of heart disease in the US in November 2021, with the aim of using digital biomarkers to help predict cardiovascular disease development. The results will inform the development of a cardio ecosystem – improving health outcomes by raising awareness, education and assessment of heart health risk and making use of digital tools to provide medication reminders and additional services – as well as the appropriate medication itself.



Huma Therapeutics' digital platform takes advantage of the increasing interest in digital tracking and management of our own health and wellness, using real-time, patient-provided health data to create 'hospitals at home' across multiple disease areas. Their app allows patients to record their vital signs, symptoms, medication and outcome measures, supporting them to better track and understand their health via their smartphone and enabling clinicians to review and monitor their status remotely. The platform also supports telemedicine appointments and provides condition-specific education and guidance, selected by their care team. All this helps to free up clinical capacity, a key aim of the self-care industry.

LEAPS by Bayer has also recently invested in <u>Ada Health</u>, a digital health company leading the way in applying AI to healthcare. Ada's <u>digital</u> <u>health assessment app</u> allows users to input their symptoms by responding to a simple series of questions, before suggesting which condition the user might be experiencing which can be discussed with their doctor. The app offers advice founded on clinical evidence and a 10-million-strong user-base, empowering users to better understand their condition and to identify the next steps to manage it themselves. While helping people better understand their symptoms now, in the future this data could help us discover insights from sub-populatoins to fuel the development of more precise medicines instead of taking a one-size-fits-all approach.

Self-care is founded on a rigorous platform of scientific investigation; with the continued development of our understanding and capabilities, even more revolutionary support for consumers' health and wellbeing may be just around the corner.

Questions for the future

With the Science of Discovery in mind, how can we best effect positive change in the self-care industry as a whole?

How will developments in the digital sphere further change the process of discovery?

Some of the best discovery work is happening in Universities. What are the most effective pathways to transfer this basic research to applied?

What can we do to better tap into discovery research happening in pharmaceutical medicine to inform R&D within the OTC space?

What ways can we partner with government scientific research agencies to tap into their basic research investments?



Chapter 5 The Science of the Consumer-Product Experience

KEY POINTS

Consumer-product experience is essential to consumer trust and can make or break consumers' ability to successfully build self-care habits.

A seamless experience begins with the initial search for information, continuing through to the physical interaction with the product itself.

Consumer-product experience can go beyond the physical item on the shelf, including both information and services.

Better consumer-product experiences can be expected to increase trust and thus enable more people to take control of their health and wellbeing.

The importance of the consumer-product experience

Science-led self-care empowers consumers to support and manage their everyday health needs themselves. At BCH, we believe the consumer is at the heart of self-care – our everyday healthcare solutions are only solutions if they are relevant and useful to the people using them, meaning that self-care products must align with consumer behaviour and expectations.

Consumer-product experience can be summarised as the way it makes the consumer feel, but it's more than a single point of interaction. Achieving a seamless brand and product experience is essential – from the consumer's initial search for information, through the brand architecture (in other words, how a family of brands links together) to the look and feel of the packaging and the physical experience of the product itself (Khan I, Fatma M. J Brand Manag 2017).

A key outcome of positive product experiences is consumer trust (Khan I, Fatma M. J Brand Manag 2017). Trust is particularly essential in the field of self-care, where consumers rely on our products to support their health and wellbeing, in the absence of a prescription and specific guidance from a healthcare professional. Product design characteristics, such as poor taste, difficulty in taking the medication itself or packaging issues, have been shown to have an effect on prescription medication adherence (Mohiuddin AK. J Clin Pharm 2019; Wilke T, et al. Value Health 2011), and patients may also take their medication in inappropriate ways to try to overcome negative attributes (Hermes Pharma). This is likely to be no less an issue for OTC self-care products.



Whatever you do, do it well. Do it so well that when people see you do it, they will want to come back and see you do it again, and they will want to bring others and show them how well you do what you do." *Walt Disney*

vvait Disney

A good self-care product should encourage people to use it when needed, not only because it works well, but also because of the simplicity and pleasantness of the experience.

Optimising the consumer-product experience

In order to keep innovating to optimise consumer-product experiences, it's essential to combine all the approaches from the previous chapters. Our increased use of digital platforms has enabled us to gain swift insights from our customers, accelerating our short-term innovation and improving our product offerings. Consumer insights are integral to the product experience, but must be paired with an understanding of the underlying biology and unmet medical need, as well as ensuring regulatory guidelines are adhered to.

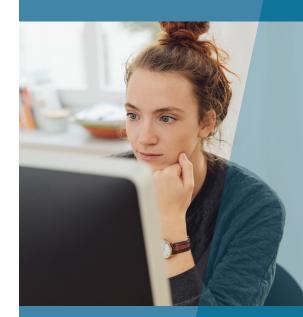
A case in point is <u>AleveX Rollerball</u>: people told us that the feel of cool metal on aches and pains felt great, leading us to develop an applicator for Aleve pain-relief lotion that incorporates three stainless-steel massage balls. <u>Alka-Seltzer</u> has long been a go-to solution to counteract heartburn after a meal, but consumers told us they felt self-conscious about taking these products for heartburn and indigestion, in their current formats, in front of others. So, BCH launched <u>Alka-Seltzer gum</u>, a more discreet option to use in company and an enjoyable experience, with a minty, refreshing flavour.

And allergy sufferers raised their frustrations with itchy throats during hayfever season, leading to the development of <u>chewable Claritin</u> – with a unique blend of cooling flavor ingredients, including menthol, for an immediate cooling sensation in the throat.

Going beyond the product on the shelf

Increasingly, we are taking a more holistic approach beyond products with regard to the full personal health journey consumers go through. More than ever, this journey begins via internet searches and increasingly includes input from digital tools like apps, sensors or websites in addition to traditional information sources like friends, family, and healthcare professionals. All of these information sources combine in a full ecosystem experience that helps consumers make more informed decisions over their self-care – and science-led self-care must take into account this entire ecosystem experience.

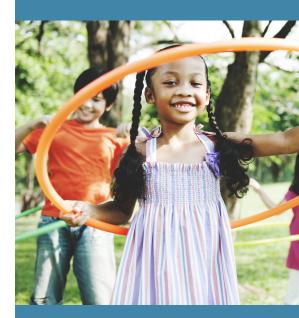
For example, younger generations of consumers have grown up with the internet at hand for health queries, and questions around health and nutrition are increasingly searched for online. COVID-19 has encouraged this trend further: particularly high rates of health-related online searches were recorded during the peaks of the COVID-19 pandemic (Du H, et al. Appl Psychol Health Well Being 2020) and searches for the term 'Vitamin C' peaked in March 2020 (Google Trends). It's essential that trustworthy information is available to consumers when they look for it and that consumers are equipped with the literacy and knowledge to know what to do with it.



This is why BCH provides both health information and learning tools within our areas of expertise to help consumers to care for their own health appropriately. In Italy, the <u>Vagina Academy</u> provides support for young women learning about intimate health and aims to overcome the taboo of discussing female intimate health and hygiene. Supported by a team of experts, the Claritin team launched the <u>Outsideologist Project</u> to encourage children to spend more time outside, with the aim of boosting their physical and mental wellbeing.

Our recent acquisition of <u>Care/of</u> is another case in point for this holistic ecosystem approach. Users are encouraged to track their progress and health status continually via an app, allowing a routine of vitamins and supplements to be increasingly better-tailored to the individual needs of each consumer's body and lifestyle. This personalised set of supplements is then delivered monthly to the consumer's door. Such services help to make healthcare easy and accessible, which is key to the future of self-care. We believe all these innovations are important steps on the road to easy and desirable everyday healthcare.

A positive consumer-product experience engenders trust and motivates the consumer to continue using the product, which is essential for a product aimed at maintaining health. Optimising this experience is therefore essential to enabling people to take more control over their self-care.



Questions for the future

With the Science of the Consumer-Product Experience in mind, how can we best effect positive change in the self-care industry as a whole?

How will the growing emphasis on sustainability affect the consumer and product experience?

Everyone's experience with a product is different. How can we better integrate diversity and inclusion into the upfront development of an effective product experience that enables people to take more control over their personal health?

What lessons can we learn from other industries that achieve high levels of satisfaction with product experience?

Conclusions and next steps

The primary aim of science-led self-care is to improve lives by making health and wellness accessible to all, giving people more control over their personal health, and helping relieve pressure on overburdened health systems. To do this, we believe self-care solutions must be rooted in science to ensure products are trusted and meet the needs of the consumers they serve. The five principles of the science of self-care, which we discuss in this paper, outline the rigorous standards we follow at BCH when developing a new product or service rooted in credible science. Not all companies follow these principles, and self-care marketing and social media is rife with fake news, unsubstantiated claims and ineffective products which serve to break consumer trust and move us farther from our goals. The regulatory environment, in some cases, can also be confusing and not fit for the purpose of increasing access to self-care solutions.

Science-led self-care is a rigorous, multifaceted process founded on the science of discovery, of the human, of the consumer, of regulation, of innovation and of product experience. It requires upfront investment to ensure products perform as anticipated and the consumer receives the benefits they expect and need. And it requires a commitment to work collectively towards a purpose bigger than ourselves.

We feel that science-led self-care is a critical enabler to a better life for billions of people around the world through everyday healthcare, and central to meeting our vision of Health for all, hunger for none. We believe adhering to these principles will enable better self-care - providing consumers with not only innovative products to support their health, but also robust information to empower choice. This in turn provides greater reassurance and confidence in the products they buy, and will help boost the reputation of the self-care industry as a whole.

The reality is that the world of selfcare is constantly evolving and there are ongoing changes and disruptors leading to further questions to explore. We've asked some of these questions at the end of each of the 'core principles' chapters, but there will always be more, and they need answers. This is only the beginning of the conversation: we are keen to enlist the help of experts across the field of self-care to find these answers. With that in mind, we are planning to hold workshops with key stakeholders, and we want to know your opinion too.

Please send us your thoughts at feedbackSOSH@bayer.com

