



Navigating the future

Annual Review 2021

PAGB

The Consumer Healthcare Association

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A message from PAGB's President

After the shock of COVID-19 and its consequences in 2020, 2021 felt at times like the 'new normal'.

Millions of us became used to working from home, to joining events via screens and to the near-impossible task of making plans more than a few days in advance.

So it is perhaps too easy to forget that the successes recorded by PAGB in 2021 were achieved in circumstances that would once have been unimaginable.

The PAGB team, led by Michelle Riddalls, worked tirelessly to address the issues affecting the consumer healthcare industry, including the ramifications of the UK's EU exit.

As the year progressed, so did the discussions with Government ministers and officials - on batch testing, the Northern Ireland Protocol, medical device regulation and more.

The positive outcomes, some of which are detailed by Michelle Riddalls later in this report, show how effectively PAGB used its expert voice on behalf of member companies and those who rely on their products.

Recognising that no-one within consumer healthcare can afford to ignore the impact of digital technology on today's business environment - particularly the extraordinary growth of social media platforms as a driver of behaviour and buying choices - PAGB hosted its Digital Week conference in July.

This five-day event was designed specifically to help companies embed digital at every stage of product development and marketing, rather than being tempted to view it as an optional bolt-on to their business model.

Throughout the week, we asked – and answered – the big regulatory questions that digital poses. How do we as companies work with suppliers and challenge competitors working in other countries and operating across borders? How can we use apps to support consumers with our products? And with more and more data available to us, how do we make the best use of real-world evidence and real-world data to support new claims or reclassifications?



It was a ground-breaking conference, reflecting PAGB's unique understanding of the consumer healthcare industry's changing needs and backed by a raft of new digital guidance for member companies.

For an organisation that has championed self care for almost half a century, 2021 was truly a milestone year for PAGB.

Together with a group of healthcare and pharmacy bodies, we published *Realising the potential: a blueprint for a self care strategy for England*, with recommendations aimed at supporting and encouraging self care across the health system.

We have called consistently for a national self care strategy but we recognised, as the COVID-19 pandemic continued to unfold, that the time was right to pick up the ball ourselves.

The joint blueprint calls for an enhanced role for pharmacy and better self care education in schools. It also recognises that healthcare professionals, as well as individuals, have a crucial role to play in increasing the adoption of self care as a positive, effective choice.

The response was unprecedented. By the end of 2021, PAGB had secured 18 meetings with policymakers, stakeholders and parliamentarians to discuss the recommendations and how best to take them forward.

Along with the many other achievements set out in our annual review, this paves the way for even greater progress in 2022 towards our overarching strategic goal: to empower self care as the expert voice of the consumer healthcare industry.

On behalf of the PAGB Board, I would like to express thanks to the PAGB team for their unstinting efforts in pursuit of that aim, and to member companies whose input is so invaluable in informing all that PAGB seeks to do on behalf of the consumer healthcare industry.



Neil Lister
President, PAGB

Neil Lister is Vice President International and Managing Director UK and Ireland at Perrigo Company plc



EU exit and beyond: leading the way for the consumer healthcare industry

A message from PAGB CEO
Michelle Riddalls

As we entered 2021, PAGB hoped for two things above all: less COVID-related upheaval and more certainty for our member companies in the wake of the UK's EU exit.

It's fair to say we were never likely to enjoy much influence over the twists and turns of a global pandemic (although we continued to provide valuable industry intelligence for those dealing with its ongoing effects).

In pursuit of greater clarity around future UK-EU trading relationships, however, we were ideally placed to help shape outcomes through the use of our expert voice.

Despite the last-minute withdrawal agreement that lifted the threat of a no-deal EU exit at the end of 2020, we knew that our member companies faced major unanswered questions in 2021 – chiefly surrounding the implementation and impact of the Northern Ireland Protocol.

Our work to mitigate the problem began on the first working day of the year, when I joined a Government-led meeting to discuss key issues for the consumer healthcare industry following the withdrawal agreement.

It was one of many such meetings with policymakers and stakeholders throughout the year, and it led in March to the first positive development we were able to report following our campaigning activity: the decision to stall and review the introduction of duplicate quality-control batch testing for over-the-counter medicines imported from the EU to the UK.

A key concern in 2021 was the risk of significant disruption to medicine supplies in Northern Ireland, under new trading arrangements which were due to come into force at the end of the year as part of the EU exit agreement.

EU exit and beyond: leading the way for the consumer healthcare industry



In October, I appeared as an expert witness before the House of Lords European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland, detailing the problems facing our members and outlining some potential solutions.

That contribution was part of a groundswell of concern about the issue, heard at the highest levels. On behalf of our member companies and consumers in Northern Ireland, we were very pleased by the EU's announcement in December that it would amend its own pharmaceutical legislation in order to protect medicine supplies in Northern Ireland, and extend the grace period delaying new trading arrangements until either those changes are in place or until the end of 2022.

As this review demonstrates very clearly, our work around EU exit did not prevent us from making notable progress in other strategic areas.

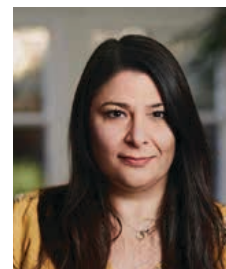


In July we held our Digital Week conference – the culmination of a digital workstream which I instigated shortly after joining PAGB in 2019 – with a raft of speakers providing invaluable insights around topics such as eCommerce, the use of real-world data, social media advertising and app development.

We launched new guidance for PAGB members across all of these areas, continued our drive to support and encourage more self-regulation by our member companies and strengthened our positive working relationships with fellow trade associations and regulators. We established an intelligence feed providing updates about environment-related issues affecting the consumer healthcare industry.

And as PAGB President Neil Lister sets out above, our work to promote and encourage self care in 2021 took us into new and exciting territory.

I would like to thank the PAGB team for their hard work in ensuring we enjoyed another successful year, and all of our member companies for their ongoing and invaluable support.



Michelle Riddalls
Chief Executive Officer, PAGB

The consumer healthcare market in 2021

Matt Carpenter, Analytics Insight Manager,
Health, Beauty, Personal Care and Home, NielsenIQ

The first half of 2021 was punctuated with milestones on the Government's road-map out of lockdown, with phased easing of restrictions leading up to so-called 'freedom day' in July.

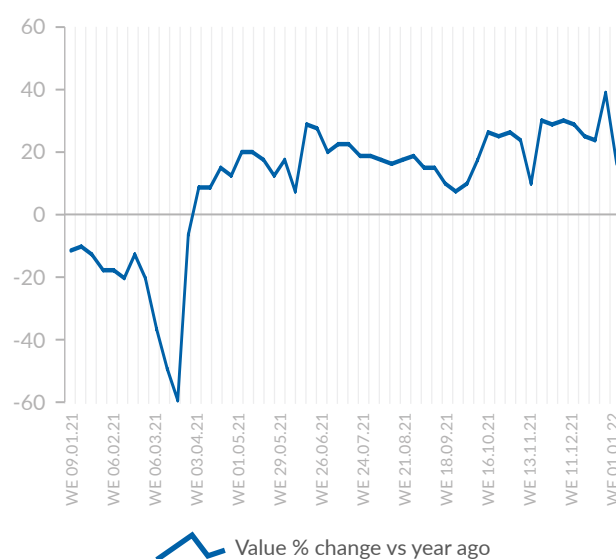
With this unlocking and a return to the 'new normal', growth in sales across all FMCG (fast-moving consumer goods) remained positive at 1.5% in 2021 despite the high benchmark of 2020 (+6.6%).

For the OTC sector, the winter of 2020/21 was difficult. Flu incidence was near-zero as consumers adapted their behaviour to help curtail the spread of COVID-19, in line with Government guidance and restrictions.

For obvious reasons, however, health remained at the forefront of consumers' minds in 2021 and the sector delivered a strong recovery in terms of value performance.

The autumn and winter of 2021 saw the return of seasonal viruses which, together with the emergence of the Omicron variant of coronavirus, drove up demand in cold and flu products (+11.9%) and pain relief products (+5.2%).

Defined OTC categories - total coverage -
weekly % change vs year ago



Overall, OTC sales grew



4.5%

in 2021, following a fall of 4.1% in 2020

(Source: NielsenIQ Scantrack)

Online, OTC sales grew



17.5%

compared with 12.5% for FMCG overall.

In store OTC sales grew by 3.2%, compared with a fall of 1.3% for FMCG overall.

(Source: NielsenIQ Homescan)

Demand for online sales was at its highest in early 2021 when more stringent COVID-19 restrictions were in place. Demand and growth for in store sales rose from May onwards as restrictions began to ease and outstripped that for online sales for the rest of the year, although consumers are not yet shopping in person at pre-COVID levels. Online demand continues to grow, however, suggesting that consumers are embracing hybrid shopping.

As we enter our third year since the first case of COVID-19, there are signs that the world is preparing to treat it as an endemic rather than a pandemic disease. While governments must decide when the time is right to start officially 'living with COVID', we know that shoppers have been defining their own '[moving on' mindsets](#) [i](#) for months, and there are some recurring themes in consumer outlooks for the OTC industry and beyond.

Disruptions drive re-evaluation



Since the start of the pandemic, consumers have reprioritised what matters to them. In fact, our recent NielsenIQ 2022 Consumer Outlook online survey reveals that 72% of UK respondents believe that their priorities, and resulting shopping habits, have been impacted to some degree by COVID-19. This includes 30% who feel they have a totally different set of priorities than in 2019. Physical wellness, mental wellness and stress management were ranked as the three most important priorities to focus on in the next 12 months for UK consumers. Given this focus on wellbeing, OTC manufacturers who demonstrate the value their brands can offer to support consumers in these areas are well-placed for success.

Where consumers shop in 2022 will be another factor to consider. With the UK returning to what feels like a 'new normal', consumers have a wide range of channels from which to buy OTC products.

The pandemic has highlighted the important role that pharmacies play in our communities. The NielsenIQ State of the Nation 2021 survey shows that 24% of consumers sought healthcare advice from a pharmacist vs 2% from an online pharmacy. Just over a third of consumers (35%) felt confident using an online pharmacist, highlighting the important role that instore pharmacies play in our communities and the benefit of face-to-face interaction and expert advice.

With ongoing pressure on health services, community pharmacists can help to relieve pressure on GPs and are also well placed to support consumers' priorities on wellbeing, offering further reasons to visit an in store pharmacy.

A cautious renewal in confidence



NielsenIQ research found that more than half of UK respondents said they were likely to continue following local health guidelines depending on the COVID-19 infection rate.

Among vaccinated respondents, who are arguably more likely to feel invested in their own safety, 23% (versus 13% unvaccinated) said they would continue to adopt stricter precautions such as wearing masks and minimising their social activities.

This underscores two key factors. Firstly, the rapidly-changing landscape as societies learn to live with COVID-19 and the potential impact of this behaviour on OTC sales in future if social interactions remain subdued; and secondly, the importance of manufacturers and retailers meeting the hygiene and safety requirements of consumers.

Inflationary pressures



The rising cost of living will be a significant factor as consumers adjust to higher prices. More than half of UK households (53%) say they are spending more on their normal weekly shop than they did six months ago. This awareness of budget pressures could lead to less socialising and more working from home to save on the costs of commuting. Consumers will look to save by moving towards discounters, purchasing own-label products and making more use of promotions. Although health is at the forefront of consumers' minds, finding the best product for the lowest available price will be a growing factor in purchase decisions.

Purchase preferences have changed since 2019



Consumers' repertoire of brands or consideration sets may look very different than previously, meaning that manufacturers and retailers cannot rely on past loyalty. They must ensure that their portfolios allow for consumers' changed circumstances. When considering what this means for the OTC industry, 33% of UK respondents in Nielsen IQ's consumer outlook survey said that, since COVID-19, affordability and lower prices were more important to their purchasing decisions. More than a quarter (27%) said they were more likely to consider the sustainability of a product before buying and 25% said they would be more likely to buy an own-label product.

Competing for share of spend will therefore be key in 2022. If a more affordable option is available to consumers, which they perceive to provide the same benefit, they will be more inclined to purchase at the lower price rather than demonstrate brand loyalty. To counter this, packaging will be an important lever to engage consumers to demonstrate the value of one company's product versus that of its competitors'. This will become even more important as retailers seek to reduce costs to help ease cost-of-living pressures for consumers.

Sustainability is increasingly important and manufacturers who can also highlight their sustainability credentials to consumers and to retailers are more likely to defend their listings.



What next?

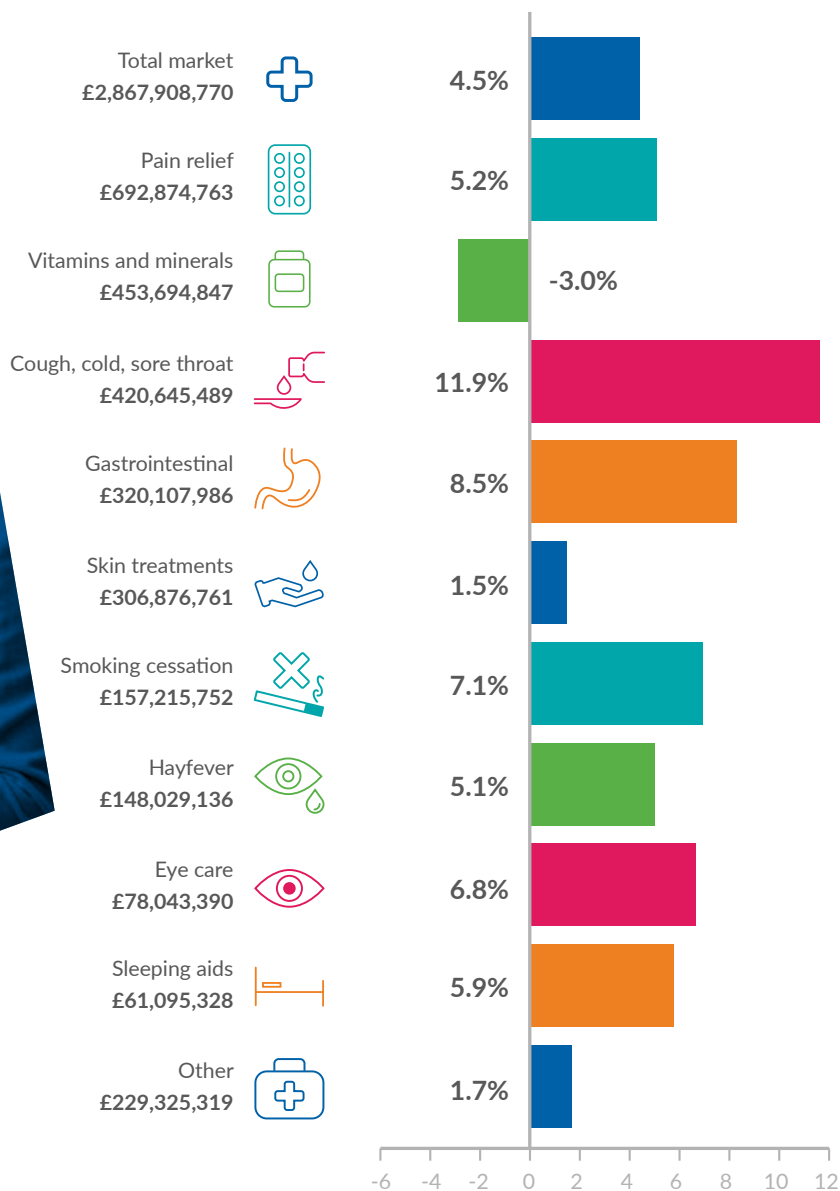
Consumers are preparing for the unexpected. With the potential for new variants of coronavirus, lingering uncertainty over any future Government-mandated restrictions and a looming cost-of-living crisis, OTC manufacturers need to prepare for a number of different scenarios in 2022. In a year when the social and consumer landscape may change rapidly, companies that recognise the importance of agility and responsiveness are more likely to navigate these challenges successfully.



Source: NielsenIQ. Total Market MAT to WE 01.01.22 NielsenIQ's OTC read was defined by NielsenIQ in agreement with PAGB and its members. It covers over 75,000 stores, including multiple and independent chemists, grocery retailers and in-store pharmacies, as well as impulse stores.



% change in value sales of OTC products 2021 (£)



NielsenIQ (formerly known as Nielsen Global Connect) is a business unit of Nielsen holdings plc (NYSE: NLSN), a global measurement and data analytics company that provides the most complete and trusted view available of consumers and markets worldwide. www.niq.com

Data and insight referenced in this review is taken from NielsenIQ's different sources

NielsenIQ is an associate member of PAGB.

Tackling the big issues of 2021



EU exit and the Northern Ireland Protocol



The impact of EU exit and the implementation of the Northern Ireland Protocol loomed large throughout 2021.

We used our expert voice consistently to share the concerns of our members at Government level, with clear and positive results.

In early January, PAGB's CEO, Michelle Riddalls, joined a meeting hosted by the then health minister, Lord Bethell, to discuss key issues for the consumer healthcare industry following the withdrawal agreement that was finally reached by the UK and the EU in the last hours of 2020.

Among them was the planned requirement that, from January 2023, over-the-counter medicines imported from the EU should be re-tested for quality control purposes before sale in the UK.



We made our case against the introduction of these new arrangements and continued to press for a rethink over subsequent weeks, with activities including:

- Raising the issue in the EU Relationship Group and at other Department of Health and Social Care (DHSC) meetings
- Meeting with the Office for Life Sciences
- Providing results from a questionnaire on quality control testing, highlighting the difficulties it would cause for the consumer healthcare industry
- Co-signing a letter to Michael Gove, then Minister for the Cabinet Office, along with the Association of the British Pharmaceutical Industry (ABPI) and the British Generic Manufacturers Association (BGMA)
- Briefing Lord Frost, then the UK's chief negotiator in EU exit negotiations, about the impact of duplicate quality control testing

Our voice was heard: in March, the Government announced that any decision to implement duplicate quality-control batch testing would be made only following a thorough review and with a notice period of two years for affected companies.

As part of that review, PAGB members were asked in November to complete an updated survey evaluating the options for batch testing; the responses will be used to help inform the next steps.

We provided tailored advice to our members on the implementation of the new UK Conformity Assessed (UKCA) quality assurance mark for medical devices, which by June 2023 will fully replace the CE mark for products placed on the market in Great Britain, and we responded in full to the consultation by the Medicines and Healthcare products Regulatory Agency (MHRA) on medical device regulation in the wake of EU exit (see page 22).

We were heavily involved throughout 2021 in efforts to ensure the Northern Ireland Protocol did not significantly disrupt medicine supplies in Northern Ireland.

Having co-chaired a 'deep dive' group set up in 2020 by the Department for Health and Social Care (DHSC) to examine the likely scale of the problem and explore potential solutions, Michelle Riddalls was invited once again to share her detailed knowledge and expertise, this time with the House of Lords European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland.

She appeared as an expert witness before the committee in October, setting out our members' fears that without a change of course, many over-the-counter medicines might become unavailable to Northern Ireland consumers.

In particular, she called for an extension of the grace period delaying the introduction of new trading regulations in Northern Ireland as a result of EU exit.



***Click here to watch
our video showing how
PAGB has supported the
consumer healthcare
industry throughout the
EU exit process***

Her evidence was later cited in a letter to Lord Frost from the sub-committee's chair, Lord Jay of Ewelme, urging Government action to help avoid disruption to medicine supplies in Northern Ireland.

We maintained our close working relationship with our pan-European trade association counterparts at the AESGP (the Association of the European Self Care Industry, of which PAGB is a member), exchanging regular information and updates about the ramifications of EU exit for the consumer healthcare industry.

In December, the European Commission announced that it would revise its own pharmaceutical legislation to help avoid long-term medicine supply problems in Northern Ireland, and that it would extend the grace period until either those changes are in place or until the end of 2022.

This was a positive result for our member companies and for consumers in Northern Ireland. We are committed to continuing our efforts in the interests of both until the situation is fully resolved.



Throughout the year, PAGB provided detailed briefing documents aimed at helping our member companies, Government ministers and policymakers understand and interpret current and potential issues affecting the consumer healthcare industry.

We shared our analysis and updates variously with the DHSC, the MHRA and the EU Commission on topics including:

- The impact of EU exit and the Northern Ireland Protocol on over-the-counter medicine supplies in Northern Ireland and the specific issues affecting OTC products
- The implications of proposed changes to quality-control batch testing arrangements
- The EU Commission's initial non-paper on medicines and implementation of the Northern Ireland Protocol, and its updated version of the non-paper
- The ramifications for medicine supplies of any decision to trigger Article 16 of the Northern Ireland Protocol
- The EU proposal in December 2021 to amend its own pharmaceutical legislation to help safeguard medicine supplies in Northern Ireland



In total, we shared 211 pieces of guidance and information about EU exit on our members-only EU exit news blog.



Our EU exit newsletter, exclusive to PAGB members, continued to provide weekly updates and intelligence throughout 2021.



Self care: a landmark year

Self care has a crucial and under-utilised role in the UK's health system. It can reduce health inequalities, improve outcomes and help to protect over-stretched NHS resources.

PAGB has long called for a national self care strategy to address the gaps in education, training and support that may deter people from practising self care.

In 2021, we went further.



Working with partner organisations across pharmacy and healthcare, we published *Realising the potential: a blueprint for a self care strategy for England*. [i](#)

The catalyst was, in part, our findings from two consecutive annual surveys in which we asked more than 2,000 people across the UK about their attitudes to self care and accessing health services.

2020

69% of people told us they would be more likely to consider self care as a first option in future in our 2020 poll, conducted at the tail end of the most stringent COVID-19 lockdown conditions.

51% of people said they would think twice before seeking a GP consultation for a self-treatable condition.

24% of people told us that their attitude to self care had changed due to the pandemic.

2021

54% By the summer of 2021, that figure had fallen to 54%.

39% of people said they would think twice before seeking a GP consultation for a self-treatable condition.

27% of people told us that their attitude to self care had changed due to the pandemic.



We recognised a clear but narrowing window of opportunity to build on the shift in attitudes prompted by the pandemic.



We reconvened the Clinical Consensus Group that first met in October 2019 to discuss how best to seize the opportunity for self care.



Our initial move - to update the group's recommendations around harnessing opportunities for healthcare innovation in response to the pandemic - was quickly followed by the decision to draft our own blueprint for a national self care strategy.

Realising the potential and its associated self care strategy website were launched on 19 October at an online event joined by more than 40 people. The document attracted national and specialist media coverage.

The response to the blueprint has been enormously positive. By the end of 2021 we had secured 18 meetings with policymakers and stakeholders to discuss the document, its recommendations and its implementation at local and national level.

Realising the potential will be the cornerstone of our self care policy and engagement work throughout 2022 and beyond.



Our joint self care strategy blueprint, *Realising the potential*, **1** calls for a raft of measures to bring about 'a wholesale cultural shift' in attitudes towards self care and accessing health services.

It recommends that:

- The Department of Health and Social Care should work with medicines regulators to identify conditions for which treatments could be switched from prescription-only (POM) to over-the-counter status, to give people faster, easier access to medicines and promote self care
- Pharmacists should be more fully integrated into the health system, with the right to update as well as read individuals' medical records
- Pharmacists should have the right to refer people directly to other healthcare professionals, so that anyone visiting a pharmacy as a first option knows it will lead them either to the best self care advice or to another appropriate expert

The blueprint says self care should be taught in primary and secondary schools and included in healthcare professionals' training curricula. It urges policymakers to use digital technology to its full potential as a way of broadening access to self care information and supporting self-treatment options.



"There is a clear desire among the public to practise self care in order to help themselves and relieve pressure on the NHS – but they need to feel able and supported to self care when that's the best option for them."

– Dr Sarah Jarvis, GP

Embracing the digital world

We all recognise that digital technology has changed life for millions of people in the space of a generation.

Our member companies need more. To thrive, they must understand what those changes mean in practice for regulation, trading and marketing across the consumer healthcare industry.

And in a world rife with health misinformation, they have the opportunity to provide consumers with accessible, trustworthy online information about self care options and treatments.

That's why we put digital at the top of PAGB's agenda for 2021 and beyond.

Our Digital Week online conference in July was the culmination of a workstream launched by PAGB in 2019 to support our members in the fields of eCommerce, real-world evidence and data, apps and medical devices, social media and digital self care.

This unique week-long event was designed to address one key question: how can consumer healthcare businesses integrate digital operations successfully at every stage?

The conference featured speakers from organisations including Google, IQVIA and the MHRA alongside PAGB's own expert regulatory and advertising team.



In tandem with our Digital Week conference, we published new digital guidance for PAGB members on the themes covered at the event.

eCommerce

What rules govern the sale of consumer healthcare products online? How and why do responsibilities change according to the type of transaction involved? What happens if you trade online across national borders?

[Click here to find out more](#) 

Real-world evidence

What is real-world evidence? How can companies use it to maximum effect? What are the opportunities to harness real-world evidence at different stages of the product lifecycle – for example, during the registration process or as part of a reclassification application?

[Click here to find out more](#) 

Apps or medical devices?

As more and more people use personalised technology to monitor their health metrics - whether to maintain wellness or monitor a specific condition, or both - what distinguishes an app from a medical device, an educational tool or advertising? What factors should regulatory teams and others consider when developing apps? How do you reach an audience for your app?

[Click here to find out more](#) 



Digital Week also provided a platform in 2021 for the launch of our new social media advertising guidance for PAGB members.

Covering medicines, medical devices and food supplements, the guidance is designed to help overcome the challenges around marketing via online platforms, including:

→ Understanding when digital content is considered as advertising

→ Using healthcare professionals, celebrities and influencers

→ Drawing content from online reviews and testimonials



Our Social Media Advertising Workshop, based on this new guidance, joined PAGB's stable of training events in 2021.

In December, we added further to our offering with the launch of an hour-long workshop covering the application of essential information to digital media.

Both will continue to be available alongside all of our workshops at heavily discounted rates for our member companies.



Enhancing and encouraging the use of digital self care tools – already a focus for PAGB – became even more important in the context of the COVID-19 pandemic.

In November, we worked in association with the All-Party Parliamentary Group on Digital Health to convene a round-table event on digital self care.

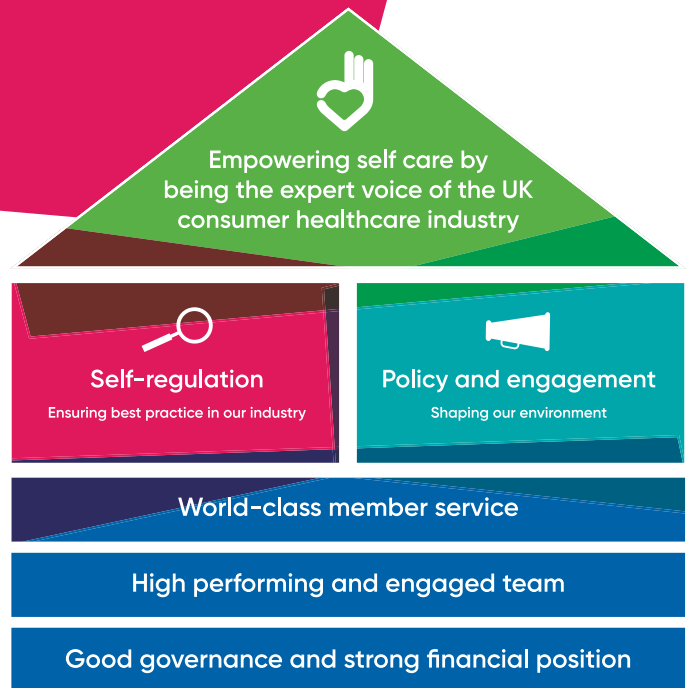
Attended by MPs and representatives from key stakeholder organisations, its aim was to consider how the COVID-19 pandemic and subsequent rapid advances in remote healthcare services have changed the digital self care landscape.

In line with one of the three core themes of the self care strategy blueprint (see page 14) we wanted to scope out the opportunities these changes might present to embed digital self care further within our healthcare system.

Delivering PAGB's strategy – a progress report

We made real progress in 2021 towards our strategic goals across all areas of work.

As always, action around our strategic priorities was informed by regular consultation and liaison with our members to ensure we continue to lead according to industry needs.



Self-regulation: ensuring best practice in our industry

Advertising



Roll-out of advertising toolkit

Following a pilot project and feedback in 2020, we updated our advertising toolkit for PAGB members in 2021.

The toolkit enables companies to self-approve certain types of advertising, as part of our commitment to improving flexibility for PAGB members without compromising the industry standards that we uphold.

We launched a programme of tailored meetings for members seeking to use this new resource, creating bespoke examples to demonstrate how each company could use it most effectively.


Our advertising compliance experts shared ideas and insights with member companies about how best to introduce the toolkit concept to their own teams as a point of reference for core claims.




Protecting industry standards

Adherence to our advertising and other codes is a condition of PAGB membership. We know it is frustrating for our member companies if and when non-members fall short of those standards.

We want to help root out marketing material and products that risk damaging the reputation of the consumer healthcare industry and which may leave our own members facing unfair competition from less scrupulous operators.

In 2021 we created [additional guidance](#)  for member companies on how to report suspected non-compliance directly to online advertising and sales platforms, following our earlier work on sharing such concerns with regulators. We encourage members needing to raise compliance issues to access this on our website.

We also liaised directly with organisations such as Google, eBay and Amazon to understand how we may be able to work together against breaches of the [industry code](#). 



Advertising in an online world



We launched our Social Media Advertising Workshop in 2021, offering new training and insights around issues such as endorsements from healthcare professionals and influencers, interaction with customers and the use of online reviews and testimonials.

In another first for 2021, we developed and presented our inaugural 'bite-sized' interactive webinar on the use of essential information in digital advertising for over-the-counter medicines, setting out the legal requirements for essential information with practical examples and guidance on exceptions.

See page 16, Embracing the digital world 

Regulatory affairs

Across Government and industry, there was no let-up in the demand for our expert regulatory knowledge.

We represented our members at the highest level as policymakers negotiated the complexities of future trading arrangements between the UK and the EU in the wake of EU exit – in particular the implementation of the Northern Ireland Protocol (see page 11).

We continued to develop our positive and productive relationship with the MHRA, meeting members of its team regularly to discuss key areas for our member companies including reclassification, medical device regulation and pack design.

We participated in AESGP regulatory affairs committees on medicines, medical devices and food supplements, to ensure we continue to understand the EU landscape and provide updates on the UK changes that are being implemented.

We were part of a group convened by the Global Self Care Federation to consider regulatory flexibilities introduced during the COVID-19 pandemic, and to recommend where these might be **embedded permanently** in order to safeguard consumer access to over-the-counter medicines.



Reclassification

We fully support making more medicines available over the counter, when they have an appropriate safety and efficacy profile.

In 2021 we re-established our Reclassification Subgroup (under the umbrella of the Regulatory Affairs Group) to work on guidance around switching products from prescription-only status.

The group drafted a potential new model for switch applications and assessments that was discussed with the MHRA.

In tandem with that project, we led a drive on behalf of the consumer healthcare industry to secure input into the MHRA's own draft guidance on reclassification, which should be available in 2022. PAGB also worked on providing guidance for companies new to reclassification about how they should assess potential candidates for switching and prepare for scientific advice meetings. This is due to be published during the second quarter of 2022.

We continued to collect data regularly from our members about potential reclassification applications, sharing these with the MHRA to aid its resource allocation and therefore help improve the service offered to companies when they submit their switch request.

We submitted responses to support switch applications by three PAGB member companies that were approved by the MHRA in 2021.

- Desogestrel was reclassified from POM (Prescription Only Medicine) to P (Pharmacy), allowing for the first time the pharmacy sale of two branded forms of progestogen-only contraceptive pill, Hana and Lovima.
- Nuromol (a combination of paracetamol and ibuprofen) was reclassified from POM to GSL (General Sales List), permitting its sale in general retail outlets.



Packaging

We re-established our Pack Design Working Group in 2021 to support progress towards our strategic goal of self-regulation for packaging and labelling of medicines.

The working group oversaw a major update to PAGB's [Medicines Packaging Code](#) **i** to reflect the latest MHRA guidance and regulatory changes resulting from EU exit.

In conjunction, the team designed and delivered our new Pack Design Workshop, the first of which featured MHRA representatives as well as our own experts.

The workshop provided a launch pad for our revamped members-only pre-vetting pack design service (known as P3 expedited MHRA approval or P3Ex).

This enables our member companies to send certain types of proposed pack design changes to the PAGB team for review before submission to the MHRA, thereby cutting the MHRA's own assessment timeframe from 90 to 30 days.

Following PAGB proposals to the MHRA, the scope of the P3Ex pack review service was widened in 2021 to include changes to the logo design on the Patient Information Leaflet (PIL).

Our new Pack Design Workshop covers this service, as well as overarching requirements for OTC medicines labelling.



PAGB members seeking advice about all aspects of packaging claims can contact us via packdesign@pagb.co.uk.





Medical devices

In September 2021, the MHRA launched its consultation on the future regulation of medical devices in the UK, with a ten-week deadline.

It asked for views on a wide range of issues including the classification of medical devices, quality management and documentation requirements and the categorisation of health-related software apps.

We set up a team to formulate PAGB's response, circulating an initial draft of our proposed contribution and then, following the input we received from members, an amended document for further comments before submitting our final response.

As the impact of the UK's EU exit continued to reverberate through the consumer healthcare industry (see page 11), we supported members in navigating the implementation of the EU's medical device regulation in Northern Ireland.

PAGB was persistent in raising concerns with the DHSC and the MHRA about the ramifications of the regulation. In the wake of our discussions, the MHRA issued an open letter to the medical devices industry ahead of implementation of the regulation in Northern Ireland from 26 May.

The letter acknowledged that there would be a period of adaptation as suppliers adjusted their processes, and stressed that patient safety and uncompromised access to medical devices remained the agency's primary aim.

It also confirmed that, as the competent authority for Northern Ireland, the MHRA would take a proportionate approach to compliance cases where there was no risk to patient safety.

Through our close association with the AESGP, we kept fully abreast of topics under discussion by the EU in relation to medical device regulation and were able to share the necessary intelligence and draft guidance with member companies.

The Medical Devices Working Group continued to meet regularly in 2021, providing expert regulatory insight and technical information to support PAGB and our members.



Safety

We continued to support our members as necessary on ingredient issues, providing regulatory advice, stakeholder communications and media statements on behalf of the industry where appropriate.

We spearheaded a joint effort with two of our fellow trade associations, the BGMA and the ABPI, to improve and enhance our involvement in the MHRA's response to safety issues affecting healthcare products.

We led the drive to create a memorandum of understanding between all three trade associations and the MHRA, in order to achieve a more consistent approach and more effective stakeholder engagement. This will be activated in 2022.

Our work on this project in 2021 brought us closer to one of our major strategic goals: that of developing a process to manage safety issues with the MHRA.

We updated our guidance document, Organoleptic Testing on Medicinal Product Formulations, which was reviewed by the MHRA and is intended to supplement our member companies' own internal processes for organoleptic testing.



Food supplements

In January we updated PAGB's Guideline on the Marketing and Advertising of Food Supplements to encompass changes in the regulatory environment following the UK's exit from the EU.

This update was reflected in new training workshops on food supplements regulation and advertising, which we also launched in 2021.

In collaboration with other trade associations, we proposed to the Government that certain aspects of nutrition legislation in the UK should be amended following EU exit, to ensure continuing alignment in the rules that apply to Great Britain and the EU and therefore avoid problems with products sold in Northern Ireland.

The DHSC subsequently launched a limited consultation on the introduction of such changes, to which PAGB responded.

We supported member companies on a range of issues affecting food supplements, including SPS (sanitary and phytosanitary) certification, the EU decision to ban titanium dioxide as an excipient and to categorise Vitamin D3 as a product of animal origin.

We continued to attend key stakeholder meetings on food, such as the Business Expert (Food Standards and Labelling) Group, feeding back information and updates to members.

We were co-founding members of an industry working group on probiotics which was set up in January 2021 to press the case for a change in UK rules to allow use of the term 'probiotics' on food and food supplements labels. We laid the groundwork for a stakeholder engagement campaign around this issue, which will gather pace in 2022.

The PAGB Board agreed in 2021 to bring into membership cannabidiol (CBD) products which meet the necessary authorisation criteria. This is subject to assessments by the Food Standards Agency, which are ongoing.

Policy and engagement: shaping our environment

We used our expert voice consistently on behalf of the consumer healthcare industry across the areas that matter to our members, shaping and influencing policy through consultation responses, communications and engagement with stakeholders and decision-makers.

We shared the perspective of the consumer healthcare industry through our responses to 16 consultations around topics including medical device regulation, the impact of the Northern Ireland Protocol on medicine supplies in Northern Ireland and amendments to nutrition legislation.



Self care

As detailed elsewhere (see page 14), in June we conducted our second annual self care survey. We asked more than 2,000 people around the UK about issues including their attitude to accessing health services and the factors that might make them more likely to seek advice from a pharmacist.

We wanted to gauge whether the shift towards self care that was evidenced in our 2020 self care survey had continued into 2021.

The results suggested people had become slightly less likely to embrace self care as a first option, although more than a quarter of respondents told us the pandemic had changed their attitude towards self care.

Our findings helped drive the creation of our shared [self care strategy blueprint](#) **i** (see page 14) to help maintain momentum towards more widespread adoption of, and support for, self care.

We backed the launch of the Global Self Care Federation's Self Care Readiness Index, which compared the UK's approach to self care with that of nine other countries around the world. The report's findings chimed with our own view that more could be done in the UK to support and encourage self care for minor ailments.





Environment

The consumer healthcare industry has a crucial role to play in supporting people to self care.

At the same time, we recognise that it is tied to processes, systems and materials that can have a detrimental impact on the environment – and that environmental protection and sustainability are increasingly important in consumers' decision-making.

In 2021, our work included:

- The launch of our environment and sustainability news and intelligence feed, along with a regular newsletter summarising the latest updates – both exclusively for PAGB members
- PAGB's pledge of support for the Global Self Care Federation's Charter for Environmentally Sustainable Self Care, committing us not only to helping our members implement more sustainable policies wherever possible but to minimising our own environmental footprint
- Research around consumers' disposal of over-the-counter medicines, with encouragement to make use of the pharmacy take-back scheme and avoid the risk of environmental contamination from unwanted products

On behalf of our members, we responded to a consultation by the Department for Environment, Food and Rural Affairs on the introduction of extended producer responsibility (EPR), under which producers will be required to pay for management of packaging around their goods once it becomes waste. We co-signed a joint position paper on the EPR with organisations including the British Brands Group, arguing for measures such as postponement of the scheme until 2024 because of delays that had already occurred in preparing for its introduction.

We continued to keep our members fully informed about the introduction of the Plastic Packaging Tax, where it will apply to their products. This follows our successful campaign in 2020 to ensure that immediate plastic packaging on human medicines is exempt from the tax.





Communications and media relations

We used our expert voice throughout 2021 to protect and enhance the reputation of the consumer healthcare industry, to promote the benefits of self care and to highlight the real and potential impact of events such as the COVID-19 pandemic and the UK's EU exit.

Continuing the recent trend away from media enquiries about specific product ingredients and towards more general topics, we dealt with five ingredients-related issues in 2021, down from 18 in 2020.

Of the broader subjects we were asked to comment on, perceived or actual problems affecting OTC medicine supplies following EU exit were a recurring theme, along with reclassification.

The MHRA's decision in 2021 to consult on, and then to approve, the reclassification of two brands of progestogen-only contraceptive pill (desogestrel) from prescription-only (POM) to pharmacy (P) status, led to widespread coverage featuring PAGB messaging.



Our statements in support of the switch were picked up by national media outlets including The Times, Daily Mail, Daily Telegraph and ITV. Our CEO, Michelle Riddalls, was interviewed about the proposal on BBC News.

Elsewhere in 2021, P3 magazine conducted a wide-ranging interview with Michelle Riddalls to mark the first anniversary of her appointment as PAGB CEO while Pharmacy Business commissioned her to write a piece analysing some of the findings of our self care survey.

The launch of our shared self care strategy blueprint in October attracted media coverage in two national outlets – Mail Online and the Daily Telegraph – as well as pharmacy trade publications.

During our Digital Week conference, the team at HBW Insight – our media partners for the event – provided in-depth summaries of daily sessions at the event: these remain available to PAGB members on our website.

Overall, we recorded 625 pieces of coverage or media mentions across all outlets in 2021.





HSIS (Health and food Supplements Information Service)



Interest in nutrition remained high in 2021 as the COVID-19 pandemic prompted more people to explore connections between diet, immunity and health.

The HSIS campaign *Immune Health – micronutrients under the spotlight* examined the role played by different vitamins and minerals in supporting immune health.

It detailed research showing that a significant proportion of the UK population fails to take in the recommended daily amount of micronutrients, potentially increasing their vulnerability to the effects of deficiencies.

A second campaign, *Back to Basics: the nutrients you need, served on a plate*, set out the facts about daily recommended amounts of nutrients and micronutrients for different groups of people, showing how difficult it can be to achieve those levels from diet alone.

Both campaigns underlined the benefits of taking food supplements where appropriate to ensure vitamin and mineral intakes are sufficient.

By the end of 2021 HSIS had secured coverage for its campaigns in national media outlets including Mail Online, The Sun, Daily Express, Daily Mirror, Metro and Sunday Mail as well as numerous lifestyle and specialist publications.

The team of advisory experts to HSIS, which includes nutritionists, dieticians, pharmacists and GPs, gave over 60 interviews on subjects relating to vitamins, minerals and supplements - more than double the number in 2020.

Overall, HSIS secured 230 pieces of proactive media coverage in 2021 and dealt reactively with 12 reputational and ingredients issues affecting the industry.

HSIS experts delivered three specialist presentations exclusively for PAGB members in 2021, on COVID-19 and the food supplements industry; Vitamin D and Government recommendations around supplementation; and an overview of the science on micronutrients and the immune system.

All three remain available on our website for PAGB members only.



Finance and operations

PAGB ended 2021 in a good financial position. New member fees, increased training revenue and reduced outgoings in 2021 contributed to this.

2021 in numbers

January – December 2021

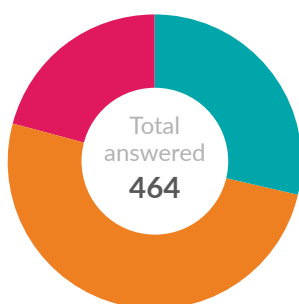
PAGB members benefit from expert regulatory and advertising advice, advertising copy clearance and training to support their business and ensure best practice in self-regulation.



For more information about the benefits of PAGB membership, watch our video here

Regulatory services

Members' regulatory queries answered



Medicines
134

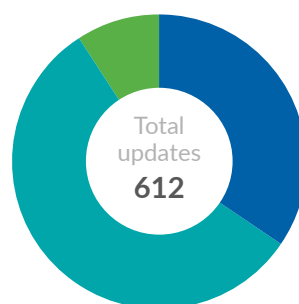


Food Supplements
234



Medical Devices
96

Intelligence updates



EU exit
211

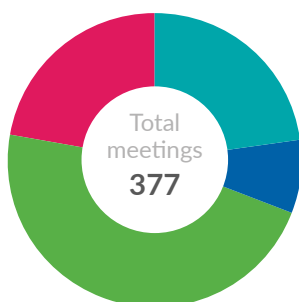


Regulatory
346



COVID-19
55

Members' meetings



Regulatory issues
86



EU exit
31

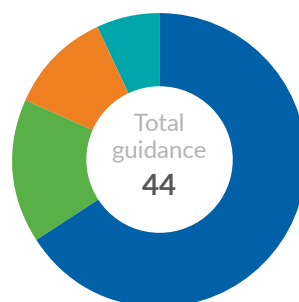


Advertising
177



Working groups and subgroups
83

Guidance for members



EU exit
29



Advertising
7



eCommerce
5



Regulatory
3

Advertising and training services

Pieces of copy reviewed

6,889



90% returned
within response
time targets

Workshops



27 PAGB workshops



Attended by **275**
participants



100% online since
March 2020

Digital Week



5 themes



15 sessions



34 guest speakers



133 delegates



727 total session views

Pieces of advertising advice



364

Representing the industry

As the voice of the consumer healthcare industry, PAGB also represents our members by engaging with regulators, wider stakeholders and media on issues affecting the industry to create a positive environment for self care in the UK.

Consultation responses

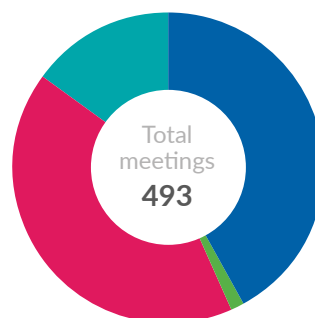


11 UK



6 EU

Stakeholder meetings



207 EU exit



7 COVID-19



206 Regulatory
issues



73 Self care

External position papers, briefings and letters



31 PAGB



11 in partnership

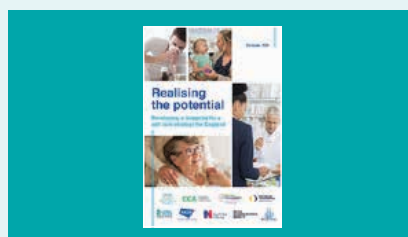
Our reports and publications make clear recommendations for action on policy issues which directly affect our members

Published reports



1 PAGB report

Self care survey 2021 [i](#)



1 in partnership

Realising the potential: Developing a blueprint for a self care strategy for England [i](#)



2 HSIS reports

Back to Basics: the nutrients you need, served on a plate [i](#)

Immune Health – micronutrients under the spotlight [i](#)

Media engagement

As the expert voice of the consumer healthcare industry, we provided interviews and statements to the media on a range of subjects including the impact of the UK's EU exit, the benefits of self care and the reclassification of medicines from prescription-only to over-the-counter status.

Media issues responded to

5
PAGB

12
HSIS
THE HEALTH AND
FOOD SUPPLEMENTS
INFORMATION SERVICE

Statements issued and prepared (proactive and reactive)

23
PAGB

12
HSIS
THE HEALTH AND
FOOD SUPPLEMENTS
INFORMATION SERVICE

Annual Review 2021

Navigating the future

PAGB

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The Consumer Healthcare Association

PAGB, the consumer healthcare association, represents the manufacturers of branded OTC medicines, self care medical devices and food supplements in the UK.