



The Consumer Healthcare Association

PAGB Highlights 2022

Contents

A message from Bas Vorsteveld, PAGB President	2
Michelle Riddalls, Chief Executive, PAGB	4
Tackling the big issues of 2022	6
MHRA performance issues and PAGB's response	6
2022 in numbers - 1 January to 31 December 2022	8
Self-regulation, including regulation and advertising	10
Policy and engagement	14
Self-care	16
Consumer healthcare industry data and insight	18

A message from Bas Vorsteveld, PAGB President

2022 was another significant year for the UK's over-the-counter medicines sector – a year in which we demonstrated our resilience and adaptability, our value to consumers and the role self-care can play in protecting the over-stretched NHS, and the importance of getting the regulatory framework right to support our sector and help it to grow.

Once again PAGB has been at the heart of shaping and responding to the most important issues affecting our sector.

As the UK finally moved out of Covid-19 restrictions we have as a sector made great strides in adapting to the new environment – embracing hybrid working, digital transformation and making up for lost time in terms of innovation.

Pressures remain in the system; MHRA capacity is an ongoing issue and I was pleased that PAGB were able to quickly adapt our strategy to ensure that MHRA performance was a key focus during the year. MHRA directors attended our June board meeting for a productive discussion on how we can work more closely together to resolve these issues. You can read more about our work with MHRA in 2022 on page 6.

At the same time there are ongoing challenges of Brexit, where despite the great progress we have made, a few outstanding issues still need fixing. Despite all of this our sector has found a way through, delivering vital products to UK consumers and working to empower people's decisions over their own health. The Government's proposals to expand the role of community pharmacies was welcome, but we still need to see more priority being given by Government to self-care and we will continue to urge the Government to take forward our recommendations and implement a national self-care strategy.

PAGB has been the indispensable voice of the sector among all of these challenges. Due to a combination of hard work, leadership and planning our five-year strategy has given us the right tools to respond and lead. As we move in to the fourth year of the strategy, we are making great progress and are on course to meet our goals.

On behalf of the PAGB Board, I would like to express my thanks to the PAGB team for all their work over the last year, and to member companies whose invaluable input informs all that PAGB does on behalf of the consumer healthcare industry.

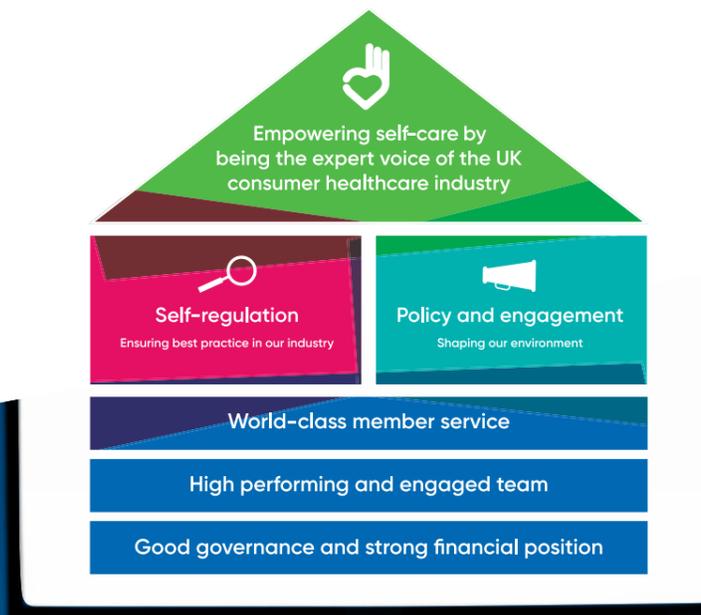
I was honoured to be chosen as PAGB President and to have the opportunity to contribute to this success – I look forward to working with many of you over the coming years to help achieve ongoing success for our truly fantastic sector and our expert voice in PAGB.

I thank you for your support and wish you well for year ahead.



Bas Vorsteveld, President, PAGB

Bas Vorsteveld is Vice President and General Manager Great Britain and Ireland at Haleon.



Michelle Riddalls, Chief Executive, PAGB

Hello and welcome to our new highlights report summarising the main achievements of the PAGB team on behalf of our members in 2022.

This year we had some huge successes in securing the regulatory future of our sector including ensuring that supplies of medicines from the EU and other countries can continue without the need to introduce import testing, and being vindicated in our approach to “non-drowsy” claims on products. We continued to provide members with vital copy clearance and regulatory support, consistently acted as a respected expert voice on behalf of the sector and refreshed our public affairs and communications with a new integrated approach designed to maximise media and political impact.



Each of the sections of this report relate to our strategy and I am proud to say that we have been making great progress on all fronts.

2022 was certainly a busy year at PAGB – with changes to the team, a continuously evolving external environment and the promise and value of our sector becoming more apparent than ever.

In December, we appointed Bas Vorsteveld from Haleon as our new President, succeeding Neil Lister of Perrigo. Neil was a fantastic ally and source of strategic input to our organisation during his term and left us on a strong footing. It is great to have someone of Bas's experience and insight ready to step up and we look forward to working with him in the years ahead.

Earlier in the year we welcomed a number of new additions to the team, yet despite the level of change the organisation has seen we have continued to deliver high quality services and advocacy for our members.

Together with Aneeta Cameron, Regulatory Affairs consultant to PAGB, I have been putting significant energy into engaging with MHRA on behalf of the sector and shaping key decisions while also keeping members informed about regulatory developments. This has included securing MHRA and DHSC attendance at PAGB board meetings to ensure that they are able to hear directly from members about the challenges they face.

Our regulatory engagement has delivered a huge amount for members this year – most notably with DHSC accepting calls from PAGB to make permanent the approach of maintaining a list of approved countries for import which require no import testing or UK Qualified Person certification. This will be extremely reassuring when it comes to supply chains and future access to medicines in the UK.

We have also increased our work in regulatory and political engagement on medical devices and food supplements.

As well as securing a big win with MHRA accepting PAGB's position on non-drowsy claims, so that accurate and fair descriptions can continue to be used, our advertising team has developed new ways to support members with compliance, including the rollout of our advertising toolkit to more members. They have also produced new guidance documents to support members with decision-making and are constantly engaging in advocacy with other key standards bodies.

And our communications team have continued to keep members informed and engaged on the work we are doing throughout the year on your behalf, with regular newsletters and increased social media activity. They have also energised our work on self-care, making more efforts to integrate our media and social media campaigns with our public affairs activity to maximise our chances, helping to gain the ear of key decision makers in Government – an approach which we started to put into effect with our self-care survey in November and December.

This report contains, as the name suggests, just the highlights of the team's achievements in 2022 and I would like to thank them for the huge amount of hard work which went into all of this. As a result we are now heading in to 2023 in a very strong place to continue to deliver outstanding and consistent value for our members and to achieve the goals we set ourselves in our strategy.



Michelle Riddalls, Chief Executive, PAGB

MHRA performance issues and PAGB's response

MHRA performance has been a concern for PAGB and its members throughout the year.

We've outlined just some of the actions we have taken, and meetings we've attended on behalf of our members to try address ongoing performance issues.

January

Michelle Riddalls met with Laura Squire, MHRA's Chief Healthcare Quality and Access Officer and Glenn Wells, their Chief Partnerships Officer to provide an overview of the issues being faced by PAGB members.

Laura Squire and Glenn Wells agreed that they would attend the PAGB board meeting.

February

PAGB published MHRA performance survey and shared findings with MHRA and OLS, Office for Life Sciences.

MHRA Medicines Industry Meeting (MIM) including discussion on what industry want from the MHRA partnerships group - MHRA express aim to expand engagement to enable delivery and operational excellence.

PAGB requested greater transparency on the agency's initiatives and pilots to allow stakeholders to know what they can get involved with.

March

Bilateral meeting where it was confirmed that Glenn Wells and Laura Squire would attend the PAGB board meeting in June.

Subsequent to the bilateral meetings with MHRA directors, Laura Squire and Alison Cave, discussed PAGB strategy responding positively to self-regulation, self-notification and streamlining reclassification.

June

MHRA workshop to explore handling of variations with a view to significantly streamline the process.

Laura Squire, attended PAGB board meeting with Liz Baker, Deputy Director, supporting her. She provided the board with an overview of plans MHRA have to overcome issues that they are facing.

July

Concerns about MHRA performance issues and response times raised again at MHRA MIM meeting. Glenn Wells reiterated it was MHRA priority to get back to greater horizon scanning and address the backlog.

September

MHRA performance raised as a priority for members during September board meeting. It was agreed that urgent action needed to be taken on MHRA performance.

PAGB established two MHRA performance taskforces (regulatory and policy) focussed on addressing MHRA performance issues.

November

PAGB initiated a joint trade associations discussion on MHRA performance.

MHRA workshop 'What makes a good quality application?' provided an opportunity for MHRA to address issues with applications and answer questions from industry.

First regulatory taskforce meeting discussed priority areas and suggestions for PAGB and MHRA actions to improve these.

Second regulatory taskforce meeting explored actions to improve priority areas further and suggested solutions including what support industry can provide MHRA.

Regulatory taskforce outputs presented at Regulatory Affairs Group (RAG).

Multiple meetings directly with MHRA to raise concerns about MHRA performance directly.

MHRA published delivery plan outlining goals for 2023 and 2024.

December

First policy taskforce meeting discussed RAG taskforce output, how to use MHRAs delivery plan to achieve key objectives and laid the foundations for a briefing document on MHRA performance.

The paper on MHRA performance and its operational ability to deliver business-as-usual activities for our members.

Trade associations again raised concerns over performance levels at MHRA MIM meeting. Trade associations emphasised the urgency and seriousness of current performance levels. The group asked for a dedicated contact within MHRA for escalation of issues and the formation of a taskforce to work on a recovery plan.

MHRA performance has been a concern for PAGB and its members throughout the year.



2022 in numbers

1 Jan to 31 Dec 2022

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.

Advertising - advice and approvals

5,892 pieces of copy reviewed

84% returned within response time targets

319 pieces of advertising advice

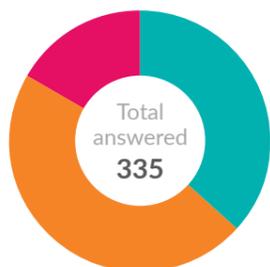
Copy submitted by type:

4,564 Standard copy

1,346 Large/complex copy

Supporting you on regulatory issues

Members' regulatory queries answered



Medicines	123
Food supplements	157
Medical devices	55

Pack design reviews
191

Ongoing ingredients issues
5

Media engagement

PAGB Pieces of coverage - PAGB

17 Negative issues
5 Reactive statements/interviews
18 Proactive statements/interviews
128 Pieces of coverage

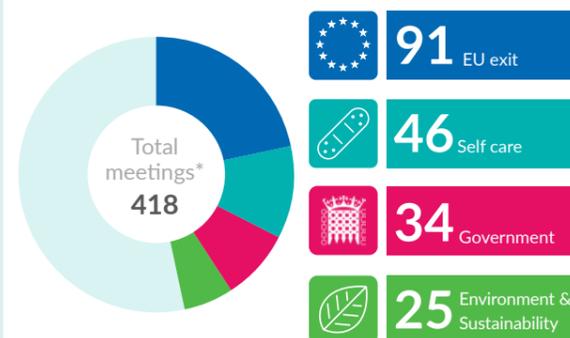
HSIS Pieces of coverage - HSIS

12 Negative issues
20+ Reactive statements/interviews
172+ Proactive statements/interviews
294 Pieces of coverage

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.

Stakeholder meetings attended on your behalf



*including meetings on other subjects (222)

Consultation responded to on behalf of all members



Position papers, guidance, briefings and letters



Supporting our members

30 Total no. of PAGB workshops run
269 participants at PAGB workshops
2 Total no. of new workshops
6 Total no. of bespoke workshops
9 Total no. of webinars run
131 Participants at PAGB webinars
325 Meetings with PAGB - supporting members to excel

Keeping you up to date

1,212 Members registered for website members' area
470 Subscribers to member newsletters
391 Regulatory intelligence updates
121 EU Exit intel via member blog
9 Environment and sustainability updates

45 Member companies are represented across the following working groups

- Advertising Working Group
- Digital Steering Committee
- EU Exit Group
- Food Supplements Forum
- Medical Devices Working Group
- Operations Group
- Pack design Sub Group
- PAGB Board
- Reclassification Sub Group
- Regulatory Affairs Group
- Self Care Group

1,033 Products listed in OTC Directory

Self-regulation, including regulation and advertising

Regulation

Regulation is one of the areas where PAGB is most clearly recognised as the expert voice of the sector. We have built a strong and trusting relationship with MHRA and have established an effective way of collaborating on behalf of our members, working to secure improvements in process and response times. We are also an active participant in regulatory discussions at MHRA trade association meetings and at the AESGP European trade association.

This has particularly been the case this year with MHRA having undergone significant transformation and looking to further work with the sector.

This includes partnership, guidance and collaborative work:



Access to medicines

Our sustained and expert advocacy over a number of years has helped secure a very positive outcome in relation to Government policy on batch testing – securing access to medicines for UK consumers and crucial supply routes for our members.



Pack design

We ran two popular and successful workshops with MHRA in attendance, helping to improve understanding and the quality of submissions from the sector – drawing on our successful P3Ex process.



Safety

We have supported members with different ingredient issues via a new, internal ingredient issue management process and have continued to work with MHRA on flexibility in implementation of regulatory requirements, while looking to align further on industry/MHRA touchpoints.

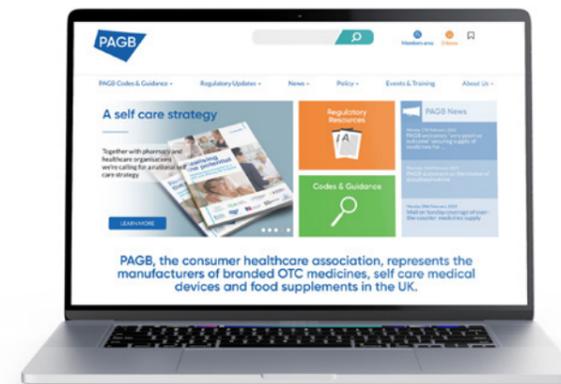


Reclassification

Having built on experience in providing advice on reclassifications, we have developed new PAGB guidance and a workshop: 'How to navigate the early stages in evaluating a POM to P switch candidate' on reclassification for delivery in the first quarter of 2023.



PAGB participated in taskforce work with other trade associations, their member companies and other stakeholders to plan and prepare for the introduction of the Electronic Patient Information Leaflet (ePIL) in the UK. PAGB have participated in intensive work including eight week sprint in September and subsequent presentation of the work to stakeholders to set out the further steps to establish a consortium of stakeholders who will take the work on ePIL forward through different development and delivery phases, seeking regulatory endorsement and buy-in from both patient, professional and healthcare organisations.



Medical devices

We have undertaken extensive analysis of the Government response to the consultation on the new UK regulations for medical devices (UK MDR). We have worked with other trade associations to highlight concerns about MHRA adherence to the established registration process for medical devices and worked with MHRA to resolve. We have also worked with other trade associations and MHRA to ensure that concerns regarding transitional times under the new UK MDR were addressed and worked with AESGP on topics relating to European regulation and Northern Ireland.



Food supplements

We are continuing to support the Probiotics Industry Working Group and leading a public affairs sub-group to seek approval of the use of the term 'probiotics' on food supplement packaging. Collectively with other trade associations we have developed extensive stakeholder maps identifying key parliamentarians to contact, drafted briefings and letters to parliamentarians.

Our CEO, Michelle Riddalls, was invited to a roundtable hosted by Maggie Throup, the then Minister for Vaccines and Public Health on vitamin D. Michelle called for all year round vitamin D supplementation.

We also developed a briefing paper on titanium dioxide and continue to monitor the situation with this ingredient.



During 2022, **191**
P3Ex reviews were carried out,
compared to **20** reviews in 2021.

Self-regulation, including regulation and advertising

Advertising

Toolkit

This year we have continued to develop the support our advertising function provides to members in a number of ways.

We have rolled out our advertising toolkit to help save members' time with copy clearance for already approved claims and to allow our team to focus our resources where they can add the most value.

We surveyed members on their use of the toolkit and those using it reported faster copy approvals and time savings as well as versatility to respond to retailer requests quickly.

The survey also showed that all members using the system wanted to continue with it, and there was wide support for the concept and moving towards greater flexibility.

All of this suggests that there is great scope for further growth in using the toolkit in future.



We have carried out our first audits of how members are using these toolkits and are encouraged to see compliance across the board.

Guidance



Our advertising team has created new guidance on best practice in advertising traditional herbal medicines, drawing on guidance and advice from other regulatory bodies and industry rulings and precedents.

We have also updated our guidance on amendments to copy permitted without resubmission; a practical document which helps members avoid unnecessary submissions, supporting our goal of greater flexibility and autonomy for members.

Compliance



In relation to compliance, PAGB has continued to shape the wider environment we operate in and to represent members' interests. As part of this activity we have continued to represent members at the European Sports and Specialist Nutrition Alliance (ESSNA) at roundtables and at MHRA Centrally Authorised Products (CAP) Borderline meetings as well as responding to the Online Programming consultation.

Non-drowsy claims



The PAGB advertising team responded energetically on behalf of members in response to a MHRA complaint report indicating that the claim "non-drowsy" was not acceptable for a non-sedating antihistamine, meaning that the term could not be used in any form for products which referenced somnolence in the Summary of Product Characteristic (SPC). The position called into question previously PAGB approved claims that such product were non-drowsy in the majority of users.

In a series of meetings and formal letters the team highlighted the distinction between consumer understanding and terminology used in SPCs, and precedent set by PAGB advertising specialists. The MHRA were receptive to the feedback and thanked us for the detailed advice we expressed as experts in the consumer healthcare industry. In light of our feedback MHRA agreed that they would not object to the use of such claims for this product.

Policy and engagement

2022 saw considerable change in PAGB's policy and engagement work – with a whole new team starting and even more political instability than the last few years.

In addition to continuing to advocate for a national self-care strategy, PAGB have remained engaged in the political and regulatory changes stemming from EU exit, we have maintained and developed our relationship with MHRA as we seek to help them speed up their process and improve services for our members.



This year has seen a marked increase in our engagement around the environment and sustainability, including running a very successful Pharmaceuticals in the Environment (PiE) webinar with an overview of the different PiE initiatives, with a focus on the impact on the OTC sector and featuring outside experts from AESGP and Astra Zeneca. We have also joined the Sustainable Medicines Partnership (SMP).

Work has also been ongoing supporting members with the implementation of the Plastics Packaging Tax in the UK and with the MHRA on regulatory issues relating to the extended producer responsibility labelling requirements this has included a specific guidance document for members.



Meeting with Steve Brine, MP, Chair of the Health and Social Care Committee



We have secured **12** interviews positioning PAGB and CEO, Michelle Riddalls, as the expert voice of the sector, including an interview with **The Times on self-care and reclassification.**



Over **470** subscribers to our member newsletters

We have continued to prioritise keeping our members engaged and informed with our range of newsletters and updates. We have also continued to position PAGB as the expert voice of our sector – with frequent media commentary on relevant events, responding to urgent issues which come up and appear increasingly on platforms to advocate on behalf of the sector.



This year we held **418** meetings with stakeholders including MHRA, DHSC and other departments, the NHS, parliamentarians, the Health Select Committee chairman and a Government Special Advisor.



HSIS has continued to inform the debate around food supplements and nutrition, and has significantly reduced negative or misinformed media coverage. We have also stepped up our external engagement on probiotics as we look to improve our external policy and media environment.



Digital remains an important area of work for us and has now been incorporated as a core part of business as usual at PAGB. We have continued to build

on the success of our Digital Week conference in 2021, providing advice and training around eCommerce, the use of real-world data and social media advertising for our members, helping to ensure that consumers can access accurate and helpful information.



Michelle Riddalls representing members at a Parliamentary roundtable

Self-care

Self-care is the action people take for themselves and their families to promote and maintain good health and wellbeing, and to take care of their self-treatable conditions. It is at the heart of our sector's mission and is a crucial part of PAGB's five-year strategy.

Working with our members and partners we have been advocating for a national self-care strategy, a strategy that will:

- empower people and to equip them with the tools to enable them to treat the symptoms of self-treatable conditions appropriately and effectively,
- help the UK develop the right structures to protect vital NHS resources, and
- reduce the number of unnecessary GP appointments and A&E attendances.



We have developed a toolkit to support Primary Care Networks and developed a vision paper for the role that digital channels can play in self-care.



This year PAGB continued to work with the Self-Care Strategy Group (formerly the Clinical Consensus Group) to bring together pharmacy bodies, medical groups and patient advocates to coordinate our efforts to improve self-care in the UK.

The strategy group has extended our engagement with the NHS, DHSC and Parliament this year – highlighting the lessons we can learn from Covid-19 and the importance of maintaining improved consumer attitudes to self-care.

People feel most confident self-treating

- Colds 94%
- Coughs 83%
- Headache 79%
- Cuts or bruises 78%
- Sore throat 77%



In 2022 we secured

18

stakeholder meetings in follow-up to the launch of the Self-Care Blueprint.

With the support of Sir George Howarth MP we secured a Parliamentary debate on self-care including a response from the then health minister recognising the important role that self-care can play.

This year's self-care survey results were written up as a thought leadership report: Taking Care, Taking Control. The report emphasised the need for Government and sector action to unleash the potential and the need to improve information to consumers and expand the role of pharmacy. This report was launched in Self Care Week and received widespread coverage in national media and trade press and was debated at a stakeholder panel event at the end of the year. This messaging is now being used to support further stakeholder engagement in 2023.



Self-Care Survey findings

This year's Self-Care Survey results showed that consumers lack the confidence to care for the most common self-treatable conditions including backaches, headaches, diarrhoea and constipation.

Over a quarter of people (27%) reported that they thought it was acceptable to go to A&E and use GP services for conditions that they could treat themselves at home.

We have produced a video setting out the progress we have made on self-care so far.

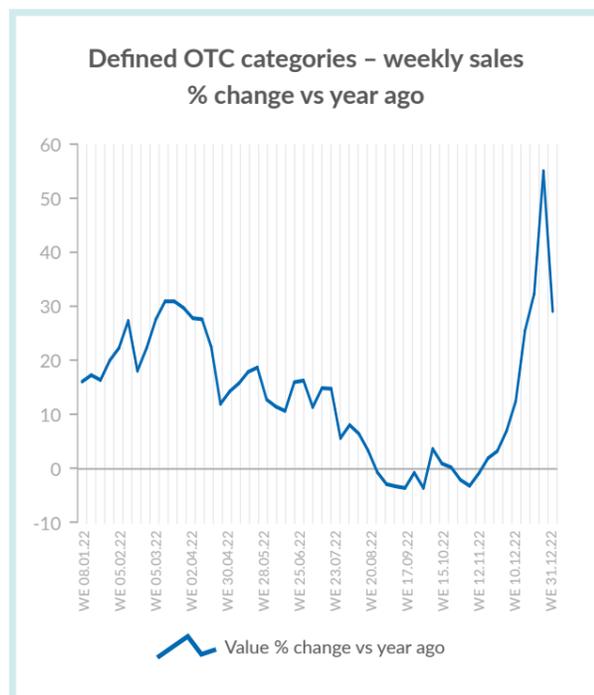


The consumer healthcare market in 2022

2022 was another difficult year, despite the recovery seen in 2021 and the worst of the pandemic being behind us, new threats emerged. Inflationary pressures grew throughout the year rising to a high of 11.7% in October and while by the end of the year we started to see a modest reduction, inflation remained stubbornly high.

High inflation resulted in an increase in interest rates throughout 2022, placing pressure on consumers' disposable incomes and contributing to a cost-of-living crisis, which has been compounded by the war in Ukraine, and the increase in the cost of energy. Supported by inflation the nominal value of fast-moving consumer goods (FMCG) sales grew by 1.4%, however unit sales fell by -4.6% as consumers reduced consumption to try to manage their budgets.

The OTC sector had a strong 2022, continuing the trend seen in 2021, despite the factors above, with the total value of sales exceeding £3,215 million and with unit sales of over 968 million.



Total value sales grew

11.0%

with unit sales increasing by **7.8%**

Inflationary pressures contributed to this growth but the OTC sector is still experiencing the effects of the pandemic. The beginning of the year saw the peak of the Omicron variant in the UK with the government having reintroduced limited restrictions in December 2021. OTC sales remained high during this period as consumers continued to focus on their health and wellbeing.

Winter is coming



As we approached September, there was increasing concern around the upcoming winter. With both Covid-19 and seasonal flu circulating, the lack of immunity in the population meant conditions were set for a so-called 'twindemic'. These concerns were heightened by the rising pressures facing the NHS including a lack of capacity, shortages of medical staff and disputes over pay driven by the cost-of-living crisis. These concerns were not unfounded as the number of patients with flu needing intensive care 'skyrocketed'* in comparison to the previous year

A media focus



The end of the year saw increased media focus on health issues; in addition to flu and covid, there were rising concerns around the rise in cases of Strep A in children. OTC sales accelerated at the end of the year driven by the pain relief and cold, cough and sore throat categories as consumers focused on self-care to manage symptoms. In addition, there were widespread media reports around potential shortages of OTC products which accelerated demand further.

The impact of the cost-of-living crisis?



Ongoing pressures on the NHS, along with the cost-of-living crisis are forcing consumers to make different and difficult decisions when it comes to their finances. However, physical and mental wellbeing remain a priority for consumers, regardless of their financial situation (NielsenIQ State of the Nation 2022). Given the performance of the OTC sector during the year, we can see that OTC is more insulated than other categories and consumers will continue to prioritise their health in 2023.

What next?



The role of the pharmacist has steadily expanded in recent years, offering additional services such as stop smoking and weight loss services.

In June, pharmacies saw over **100,000** patients, an **83%** increase on the previous year**

The role of pharmacists will continue to expand, playing a key role in relieving pressure on the NHS. Pharmacists are well placed to support consumer priorities around physical and mental wellbeing, demonstrating the vital role pharmacies can play in our community. Ensuring distribution into this channel will be even more important as the role continues to expand.

*NHS England » Two thirds increase in hospital flu cases amid rising staff absences and pressure on NHS 111

**NHS England » High street pharmacists treat thousands more people for minor illnesses

PAGB Highlights 2022



Source: NielsenIQ. Total Market MAT to WE 31.12.22 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.

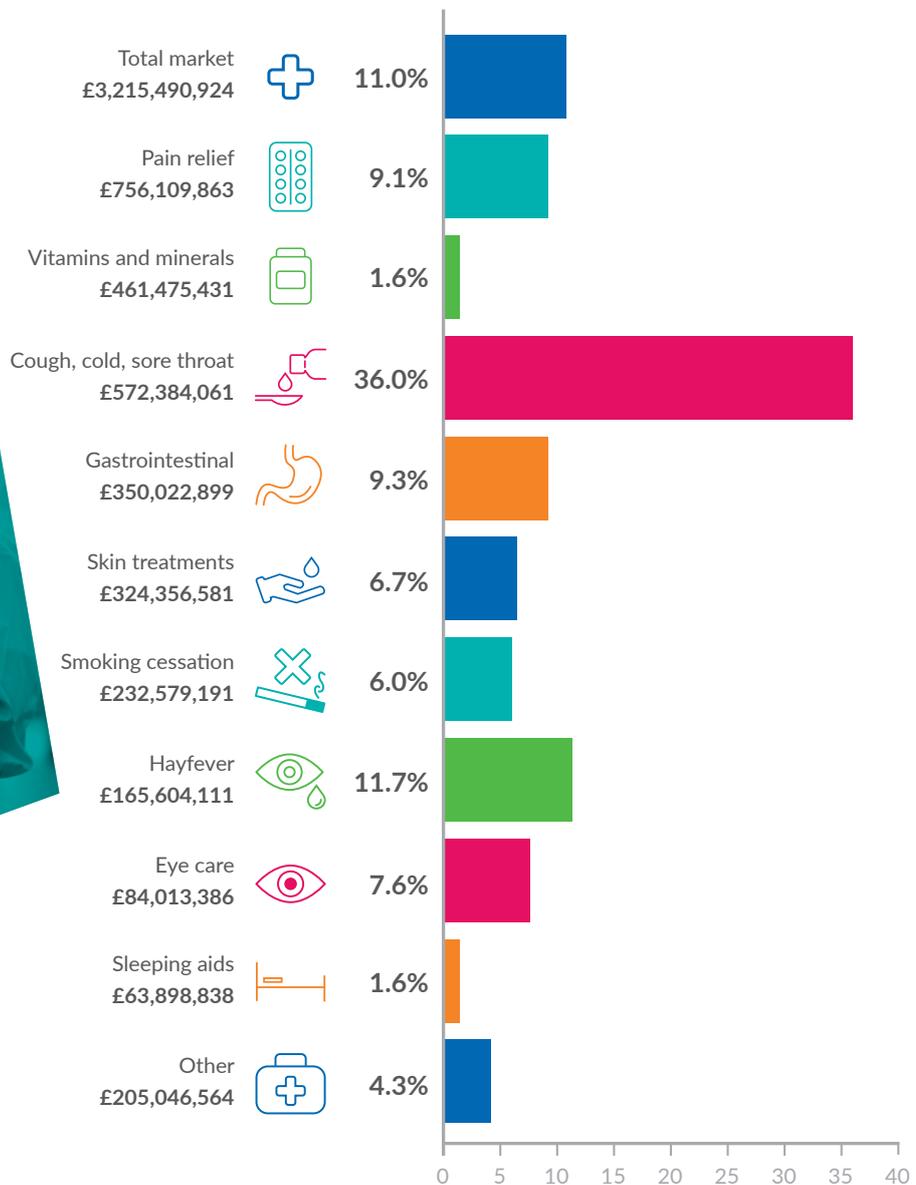


NielsenIQ (formerly known as Nielsen Global Connect) is a business unit of Nielsen holdings plc (NYSE: NLSN), a global measurement and data analytics company that provides the most complete and trusted view available of consumers and markets worldwide www.niq.com

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

NielsenIQ is an associate member of PAGB.

% change in value sales of OTC products 2022 v 2021 (£)



Matt Carpenter, NielsenIQ

Analytics Insight Manager | Health, Beauty, Personal Care & Home