

Shaping the future. Together.

Annual Review 2019



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Celebrating 100 years of CONSUMER HEALTHCARE

The world has changed significantly since the first fifteen founding members of the Association of Manufacturers of British Proprietaries met at the Cannon Street Hotel in June 1919. Since then, we've seen the introduction of the NHS, the Medicines Act, the UK's entry to and withdrawal from the European Union and the proliferation of consumer advertising thanks to technological innovation and societal change.



Our founding members wouldn't recognise the industry we know today. However, throughout all this, PAGB has been a constant.

We've upheld standards in advertising regulation and pushed for regulatory change that enables greater access to medicines. We've championed self care and supported our members every step of the way.

We're proud to celebrate 100 years of consumer healthcare, and we'd like to thank all the staff and members, past and present, who've made that possible.



Visit: www.pagb.co.uk/about-us/100-years-pagb/ to learn more about PAGB's impact over the last one hundred years.

"I would like to offer my warmest congratulations to PAGB on reaching its centenary milestone. Institutions don't survive and thrive for that long unless they're effective. That means having a strong mission and vision, clear-sighted governance and an ability to adapt to change."

Guy Parker, ASA

"Warmest congratulations to PAGB on your centenary. One hundred years of supporting the promotion and protection of public health through responsible self care is a magnificent achievement."

We look forward to continued collaboration to foster innovation and optimise tried and trusted medicines, while providing the right information for everyone to look after themselves and their families safely"

Dr June Raine, MHRA

2019

PAGB celebrated 100 years of consumer healthcare

"Congratulations to PAGB on reaching its century! PSNC is delighted to have had a long and close relationship with an organisation that has long been a supporter of community pharmacy's role in self care. We look forward to continuing this collaboration in the coming years as pharmacy's role in helping people to stay healthy is reinforced through the NHS Long Term Plan."

Simon Dukes, Chief Executive, PSNC

PAGB

Shaping the future. Together.

Annual Review 2019

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Message from the
President and
Chief Executive.

PAGB Then, Now, Tomorrow

It isn't often you get to celebrate a milestone as significant as a centenary. 2019 gave us the opportunity to celebrate the achievements of the past and the motivation to build on that heritage as we enter our second century, which we did under the theme of 'Shaping the future. Together'.

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The centre-piece of our centenary celebrations was a fantastic gala event which we were delighted to host at the Science Museum in London, 100 years to the day from the first meeting of our association. We were joined by politicians, government officials, journalists, colleagues from other trade associations as well as staff and members, past and present. It was an incredible evening, which you can read more about later in this review.

The core work of PAGB continued as we supported members with advertising and regulatory issues, helped companies prepare for the UK's exit from the European Union and campaigned for policies that will empower more people to self care.

This was the final year of our 2017-2019 strategy, the aim of which was for PAGB to be recognised by its stakeholders for shaping the consumer healthcare market. Building on the work of previous years, this focus on external engagement enabled us to deliver the goals we set ourselves in 2017 to support self-regulation, be the voice of the industry, promote self care and deliver a world-class service to our members.

In 2019, we provided ongoing and detailed support to members to help them prepare for three potential departure dates from the European Union. We worked with Government and PAGB member companies on contingency plans to ensure the continued supply of OTC products in the event of a no-deal exit, which ultimately, and fortunately, didn't happen.

PAGB published a Self Care White Paper, in March 2019, describing the ways in which Government and the NHS should implement self care policies to deliver on the objectives of the NHS Long Term Plan and release efficiency savings of £1.5 billion a year back into the system. This important policy document firmly established our policy priorities and has been welcomed by key stakeholders.

Our now full-strength advertising services team supported members to adapt to new and updated Codes, and introduced a more flexible approach to medical devices, while still reviewing almost ten thousand pieces of copy, including an increasing amount of digital advertising. We adopted a new CRM system to help trace submissions through the review process and organise member and product information. The new system will improve consistency and enable PAGB to monitor trends in submissions.



Neil Lister,
PAGB President



John Smith,
Chief Executive

We were delighted, in June 2019, to welcome Michelle Riddalls to PAGB as Senior Director for Regulatory Affairs and Advertising Services. Michelle is one of the UK's leading experts in consumer healthcare regulation and a specialist in POM to OTC reclassification. Her experience is already proving invaluable to member companies. New regulatory colleagues reinvigorated the regulatory function and helped PAGB raise its profile with regulators and stakeholders.

Behind the scenes we have continued to develop our systems and processes to offer members a fast and efficient service. We changed our IT supplier and improved our IT infrastructure, we introduced credit card payments on our website to enable faster booking for training and other resources and we implemented a new finance package for managing our accounts, which, together with some careful financial management, meant we delivered a small surplus at the end of the year. We continue to strive to deliver value for money for our members.

Our annual member survey results were incredibly positive.



90% of members say they are satisfied or very satisfied with PAGB's leadership, up 4% from the previous year, and 82% agree we deliver a world-class member service.

There are always ways we can improve, and we will work on those areas highlighted by the survey, but overall, it is great to receive such positive feedback on our work.

Looking back over the achievements of the last 100 years has given us even greater motivation to ensure we continue to deliver for our members in the coming years. During 2019, PAGB invited members and industry experts to look five years into the future at what the world, and our industry, will look like and what PAGB needs to do to respond to the changes ahead. The result was a new strategy, which was approved by the Board in September 2019, to **empower self care by being the expert voice of the UK consumer healthcare industry**, focusing on the two key areas of **self-regulation and policy and engagement** to take forward work that will help create a positive external environment for members. Among a set of challenging objectives, the PAGB Strategy to 2025 includes a new digital work programme which will support members in navigating new technology and what that means for the future of our industry.

We would like to thank PAGB's dedicated staff for their hard work and commitment and our member companies who have contributed to working groups and supported key projects throughout the past year.

As we move into a new decade of different challenges and opportunities, we are confident PAGB is in a strong position to represent the interests of its members and shape the future of self care.

The consumer healthcare market in 2019

This year has been a very positive one for consumer healthcare. Market growth has accelerated vs previous years, demonstrated by a value increase of 5.0% alongside a 1.8% increase in volume. The growth is exceptional, especially in comparison to the general slowdown in total FMCG sales which in 2019 experienced declines in value and volume of 0.7% and 1.3% respectively. We can confidently conclude the consumer healthcare market is looking much healthier.

The most important factors at a macro level are price and seasonality. The latter, while difficult to predict or influence, always has a significant impact because of the sheer size of seasonal categories.

Category leaders in 2019

Pain relief is the biggest driver of growth this year. Still the largest segment, the category was worth £628m in 2019, increasing 9.3% in value vs 2018 and contributing £53m towards total market growth. Volume also increased but at a slower rate of 3%. It is encouraging to see that such a large segment of the market, arguably the most developed and the most commoditised, with strong presence of private label and generics, is creating so much value growth.

The cough, cold and sore throat segment was the second fastest growing at 6.7% in value and 4.1% in volume, with strong seasonal demand driving this growth across all key sub-categories. The cold and flu season tracked significantly ahead of last year and ahead of the five-year average, especially during October and November. All key sectors posted growth, with cough liquids and sore throat products growing slightly above the total segment.

The third largest category by volume and value was vitamins, minerals and supplements. Encouragingly, we saw retailers giving more space to this category in 2019. Promotions continue to be important but are no longer seen as a way to grow; however, vitamins should continue to do well in the long term as the category is well placed to respond to consumer demands and expectations around wellness.

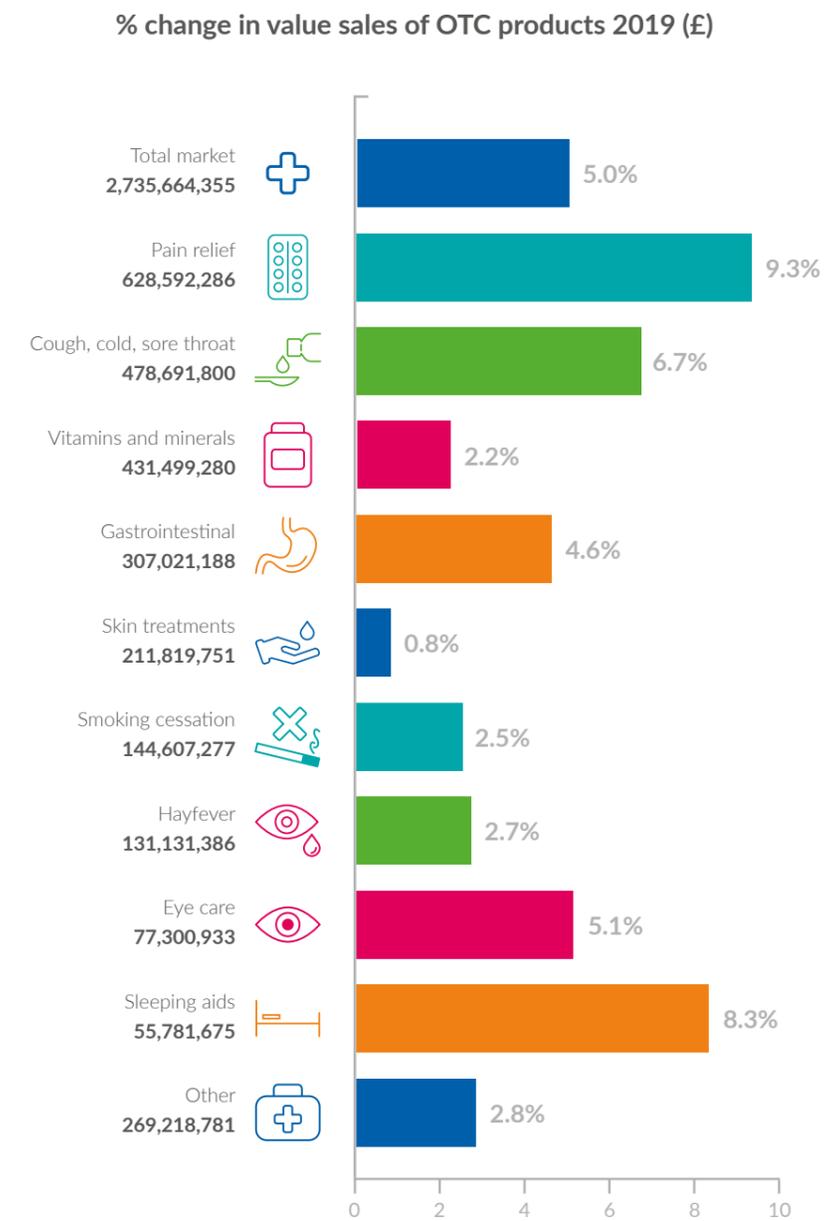
A blurring of the line between beauty and consumer healthcare

In 2019, skin care products continued to underperform with a 3.2% decline in units and only marginal growth in value (+0.8%). Recent year on year data shows that there is nothing unusual about this performance in consumer healthcare. However, if we expand the view to look at skincare in a wider context, beauty skincare is in strong growth. Consumer healthcare brands should note that in beauty, growth is coming from niche and specialist brands which reflects shifting consumer priorities to focus on 'what is good for me', particularly related to ingredients. This suggests that the line between beauty and medicated skincare is beginning to blur and could go some way to explaining the underperformance of OTC skincare products.

What next for consumer healthcare?

As we see from the data, this year paints a very positive picture of consumer healthcare and should be welcomed. It is worth reinforcing that the reliance on seasonality is high and a strong Cold & Flu season this year created a lot of growth vs 2018. While this is positive, next season will be a watch out. It is difficult to predict the severity of the cold and flu season; more challenging will be to sustain the growth experienced in 2019. Value creation is essential to continued growth across consumer healthcare and retailers and manufacturers will need to keep a sharp focus on premium products that enable consumers to 'trade up'.

Commentary and analysis provided by **Vitaliy Zhyhun**, Head of Analytics Health, Beauty & Personal Care, Nielsen January 2020



nielsen

Source: Nielsen. Total Market MAT to WE 28.12.19

Nielsen's OTC read was defined by Nielsen 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.



1968

The Medicines Act introduced classification of medicines into POM, P and GSL, establishing the OTC categories we use today

Shaping the future of self-regulation

PAGB's Codes of Practice set out the rules for advertising of consumer healthcare products, ensuring our members are clear about how to remain compliant with advertising regulations when promoting their brands. That the industry has successfully retained its self-regulatory status for a hundred years is in large part down to the ongoing relevance of its Codes and the commitment of PAGB members to following them.

Medical Devices Consumer Code

PAGB's guidance on medical devices advertising was brought up to date and expanded to address the requirements of the Medical Device Regulations. We were the first in the industry to act on these new regulatory requirements to help prepare our members in advance of implementation in 2020. The Code ushered in a new way of working with members on Medical Devices copy, which applies a member-focused approach to compliance, reducing pressure on members by removing the requirement for pre-publication approval from September 2019.

The result was a significant reduction in the number of pieces of submitted copy for medical devices products (see below).



The new Code has been recognised by medicines regulator, MHRA and advertising regulator, CAP/ASA, as a good example of how updated guidance should look.

To help members adjust to the new Code, we ran special training courses for those named accountable for medical devices compliance in member companies and introduced a new regular workshop on the Medical Devices Consumer Code for all members and associate members.

The social media landscape continues to evolve and PAGB is supporting our members to adapt. In 2019 we began a review of our social media guideline which has now become a key advertising project in PAGB's new digital strategy and will continue into 2020.

We've continued to nurture close working relationships with key stakeholders such as the MHRA and CAP/ASA while broadening our horizons and meeting with leading digital players such as Google and Amazon. Our aim is to better understand the changing parameters our members are working within and to ensure that our guidance is fit for purpose across all media.

Advertising tool kit – piloting an agile approach to approvals

The volume of advertising copy submitted to PAGB has increased over the years, as new product categories have been introduced and technology has offered opportunities for reaching consumers in different ways. Digital advertising has brought particular challenges for members and PAGB relating to the quantity and immediacy of online content.

PAGB's advertising services team, working with members on the Advertising Working Group, has developed a new agile approach to the current approval process. The aim is to make it more efficient for members and PAGB, while maintaining our high standards and ensuring the ongoing integrity of our self-regulatory function.

Following consultation with the Board and relevant working groups throughout 2019, PAGB developed a pilot scheme for medicine and food supplements advertising to enable participating members to submit campaign tool kits for approval; members then self-approve materials based on the tool kit. Members must continue to ensure that all materials are compliant with the content of relevant PAGB Codes but each piece of material will no longer need to be submitted to PAGB for approval. The tool kit pilot will run throughout 2020 and results will be used to inform future development of the copy process.

Supporting innovation in the industry

Working on new campaigns and products is always a highlight for the copy clearance team. In 2019 we supported PAGB members to get their claims and ads ready for the launch of innovative new products.

New member Kind Consumer launched Voke, an NRT product with a creative new design.

"PAGB were an incredible source of support in helping us get the initial campaign for Voke over the line in time for launch."

James Cotterell, Kind Consumer

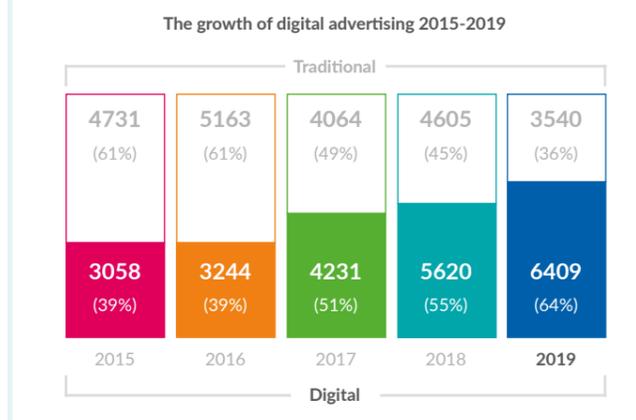
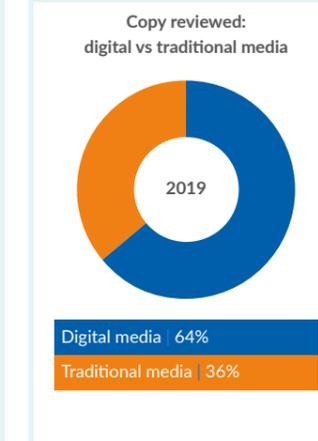
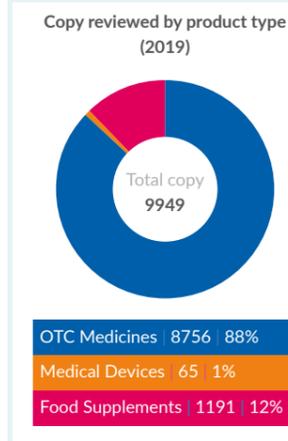
The copy clearance team helped RB navigate the launch of a new food supplement under the Optrex Brand, ProVision Eye Health.

"In 2019, we worked collaboratively with PAGB on compliance to ensure the successful launch of Optrex Provision. The time prior to launch was key for the business in terms of review and approval of a large volume of consumer and HCP advertising. The successful launch of the first VMS in the Optrex portfolio with great claims in advertising was a direct result of the partnership and collaboration between PAGB and RB medical!"

Kam Sandhu GPhC MPharm, RB UK Commercial Ltd



While there was no noticeable change in the total amount of copy in 2019 compared to the previous year, this hides significant increases in some categories, which were offset by medical devices copy being removed from the process in 2019.



New and updated guidance in 2019

- Promotion of lidocaine-containing products (guidance)
- Verification (advice)
- Social media influencers (advice)

We guided members through changes on a wide range of issues, including a radical ASA ruling on social media influencers in July 2019. We worked proactively to inform affected members and created guidance to share with marketing and medical affairs teams, updating it as we engaged with the MHRA to establish new positions.

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1936

PAGB published the world's first self-regulatory advertising code

Regulatory affairs – key projects in 2019

2019 was a year of positive change in the regulatory team. We welcomed three new colleagues who brought valuable experience and knowledge from industry, pharmacy and the regulator. This has enabled PAGB to better understand and influence the regulatory environment in which our members operate.

Our priority this year was to build strong foundations that would improve the regulatory support available to members. We set out to:

- build a respected, collaborative and engaged relationship with regulators and other key external stakeholders
- develop a new regulatory strategy in line with the overall PAGB five year strategy
- put members at the centre of our strategic planning (Regulatory Affairs Group)
- communicate with members on regulatory meetings attended and on-going activities

Shaping the future of access to medicines

It was another quiet year for reclassifications with five reclassifications, including one product – a screening test for potential allergies to an ingredient in hair dyes, which made the jump from prescription only to GSL.

Looking to the future, we opened discussions with the Medicines and Healthcare products Regulatory Authority (MHRA) on PAGB's ideas for new switch pathways, as set out in our strategy to 2025. We were pleased that our proposals for reimbursable switches and different switch models were received positively and we agreed to support MHRA in evaluating existing switch models through PAGB's reclassification sub-group, which will be re-established in 2020.

Switches in 2019

5 reclassifications

1 POM to P



1 POM to GSL



3 P to GSL



Pack Design – getting it right first time

PAGB provides an expedited pack design review service enabling companies to make a P3 submission to MHRA following PAGB review, which shortens review timelines. In 2019, we worked with the regulator to identify and implement improvements in processes. The aim is to achieve greater alignment to help meet our shared goal of increasing the approval rate and right-first-time submissions.



38 Pack design assessments in 2019.

We established a regular programme of meetings with MHRA to improve coordination and quickly address any arising issues to smooth the process for our members.

Defending the industry on ingredient issues

PAGB's regulatory affairs team continued to support members on ingredient and safety issues through close and ongoing contact with the regulator throughout 2019. We assisted members with their responses to letters from MHRA and CHM, and commissioned reports to build an evidence base in response to regulators' concerns. We have helped enable more proportionate actions to be taken on actives and ensured that there was continuity of supply of product for patients through implementation of pragmatic solutions.



10 ingredient issues in 2019.

Going forward, we intend to develop a more robust way of working with the MHRA to manage ingredient issues in a proportionate, evidence-driven manner, to achieve the best risk-benefit for patients. Significantly, an external safety process is in development, with talks with other trade associations (BGMA and ABPI) to develop a cross-industry process with the regulator initiated in December 2019.

PAGB contributed to an ingredient challenges database managed by The Global Self Care Federation, enabling member associations to get a broader view of emerging ingredient challenges across the world.

Meetings and stakeholder engagement

The regulatory team coordinated working group meetings for the Regulatory Affairs Group (RAG) and Medical Devices Regulatory Group (MDRG).

A large part of our work involves attending meetings with stakeholders to ensure PAGB's voice is heard on key issues affecting the industry. At our annual bilateral meeting with MHRA we agreed current and future partnership working to achieve common goals.

A selection of external policy-related meetings we attended in 2019:

- Medicines Industry Group (MIG)
- Office of Life Sciences (OLS) on medicines and medical devices regulation post-EU Exit
- DEFRA / Environment Agency on Pharmaceuticals in the Environment and the Water Framework Direction
- ABPI Plastics Tax Workshop
- AESGP Regulatory Affairs Committee; Pharmacovigilance Committee; Medical Devices Committee; and Annual Conference
- Department of Health and Social Care – EU Exit Trade Readiness Webinar

Plastics and the future of packaging

In 2019 the Government set out proposals to introduce a tax on single-use plastics and its plans for reforming the UK packaging responsibility system. PAGB alerted members to the plans and quickly set about establishing a position for the industry to inform our response to the consultations.

We brought together trade associations from the plastics industry, medicines, cosmetics and nutrition for a meeting to discuss concerns and share information. We also joined cross-industry discussions with the Treasury at a meeting organised by ABPI.

To make the case to the Treasury, PAGB and its partners developed clear arguments to explain the immediate difficulties of using recycled plastics for medicines and devices and produced a timeline showing how long it would take to develop a suitable new plastic.

Regulatory advice to members in 2019

PAGB members can seek advice from the regulatory team on issues relating to products in membership or in development. Contact regulatory@pagb.co.uk for more information.



66 OTC medicines



63 medical devices

Pieces of advice given in 2019 (by email, telephone, face to face)

We responded to consultations including:

- Guideline on the environmental risk assessment of medicinal products for human use
- Key principles for the electronic product information of EU medicines
- Restricting the use of intentionally added microplastic particles in consumer or professional use products of any kind
- A reclassification public consultation

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2007

The Better Regulation of Over-the-counter Medicines Initiative (BROMI) reduced red tape and increased access to medicines

Countdown to MDR implementation

Work to prepare our members for implementation of the Medical Devices Regulation (MDR) in May 2020 remained a major focus in 2019.

A new classification rule introduced by the MDR (Rule 21) relates to substance-based devices. This is a category that applies to many self care medical devices in PAGB membership. PAGB's Medical Devices Regulatory Group worked extensively on this issue, collaborating with our European association, AESGP, to prepare a position paper for the interpretation of Rule 21. PAGB discussed the paper with MHRA and the relevant notified bodies, before sharing it at meetings with the European Commission to help inform work by the Commission's borderline and classification working group, which is responsible for the development of MEDDEV guidance.

Work on other MDR issues – UDI, Safety evaluation (article 12.2) and Rule 14 also continued in 2019. Members from the Medical Devices Regulatory Group took on lead roles in twelve workstreams established by PAGB to review specific areas of guidance related to the implementation of MDR. This involved all members of the group in providing feedback on the MDR plans and the potential impact they may have on the UK market and their companies. The workstreams ensure that all areas are covered and that PAGB is well prepared to respond in an agile way to developments.

The regulatory team provided detailed advice to members on MDR-related issues such as levomenthol in cooling gels for pain relief, and changes to medical devices regulation as a result of EU Exit.



Voice of the industry on medical devices

With the input of members on the Medical Devices Regulatory Group, PAGB provides specific feedback to government departments on the real impact of regulatory requirements on industry. In 2019, PAGB met with officials from the Department for Business, Energy and Industrial Strategy (BEIS) and the Office for Life Sciences (OLS) to communicate three key barriers preventing manufacturers from meeting MDR implementation deadlines.

PAGB members invest their trust in PAGB to represent them in confidential discussions with the regulator. As a result, in 2019 PAGB was able to take industry concerns to MHRA including sharing details of EU Exit readiness and MDR preparedness. PAGB used these meetings to highlight the need for flexibility in the UK for manufacturers to maintain products on the market.



A selection of external policy-related meetings we attended in 2019:

- Medical Devices Industry Liaison Group (MDILG)
- AESGP Medical Devices Committee
- Medical Devices Anticounterfeit Forum
- BEIS-MHRA-OLS meeting, submitting a paper on 'Key Consumer Healthcare Industry Readiness issues on MDR' to MHRA
- MHRA-DHSC-OLS Medical Device Economic Partnership Workshop

PAGB and its members provided input to a number of significant consultations including on quality requirements for drug-device combinations

PAGB's Medical Devices Regulatory Group is an active and effective group that works on behalf of all members with medical device products.

"It's a small group with a big heart – always ready to get involved and influence others to effect change."

Linda McLaughlin,
The Mentholatum Company, Chair, Medical Devices Regulatory Group

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2014

Self care medical devices were brought into PAGB membership for the first time

New challenges in food supplements regulation



In 2019, PAGB saw a trend towards members introducing or expanding their food supplement product ranges. This can be partly explained by companies focusing on a broader range of products that appeal to consumers' growing interest in health and wellbeing.

Advertising guidelines

PAGB provided members with regulatory advice on labelling and advertising to support compliance with our guidelines and the many regulatory requirements that apply to food supplements. We reviewed our food supplements labelling and advertising guidelines, seeking input from across the membership to ensure they are clear and fit for purpose. The final guidance will be published in 2020.

Industry collaboration on food additives

We have been actively working on our response to EU updates on Food Additives both on Category 17 and additives for infants and young children, which has implications for products in the UK for children under 3 years of age.

PAGB and colleagues from the Council for Responsible Nutrition (CRN) and the Health Food Manufacturers Association (HFMA) have worked closely to develop a cross-trade association position on this topic. In December 2019, PAGB, CRN and HFMA met with the Food Standards Agency to ensure that officials were aligned to our joint stance on these issues.

A voice at the table

PAGB regularly participated in meetings with stakeholders to ensure the voice of the consumer healthcare industry was heard by government departments and regulatory bodies, including:

- CAP Borderline meetings with MHRA/ASA and other relevant stakeholders
- Business Export Group on Food Standards and Labelling
- Business Reference Panel (Office of Product Safety and Standards)
- Industry Non-Compliance Round Table
- Herbal Forum
- AESGP Food Supplement Group Meetings
- Food and Drink Federation (FDF) EU Exit Roundtable

A close eye on ingredient issues

PAGB has closely followed developments in Europe on two key ingredient issues: Titanium Dioxide (TiO₂) and Cannabidiol (CBD), sharing intelligence with our members to support their own commercial decisions.



Titanium Dioxide: unilateral action in France to ban TiO₂ from "food stuff" products has prompted concerns throughout Europe on the potential for wider regulatory control of this ingredient. Through active membership of AESGP, we have kept our members up to date on this topic and input to AESGP responses as required.



CBD: added to the EU Novel Foods Catalogue in 2019, this ingredient has been widely included in products across many sectors, including consumer healthcare. PAGB has kept a close watch on this issue, updating our members on new developments. We've been in discussions with regulators to understand their positions and will produce our own position paper on CBD and its status in 2020.

Food Supplements Forum

Food Supplements Forum members met four times in 2019 to discuss updates on food supplements regulation and to guide PAGB's approach to these. Also, in 2019 the Forum welcomed guest speakers – experts from the Health and Food Supplements Information Service (HSIS) – to share latest research and trends.



- Dr Emma Derbyshire on her peer review paper into dietary trends over the past 20 years (March)



- Dr Emma Derbyshire on plant-based diets; dietary trends and nutrition policy (September)
- Dr Chris Etheridge on trends and challenges on the horizon for VMS & Botanicals (December)

PAGB and its members provided input into significant consultations including on proposed amendments to nutrition regulations as a result of EU Exit; fortification of flour with folic acid; and the UK's future food strategy.

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1989

PAGB extended its remit to cover food supplements products

EU Exit: Supporting members through uncertainty

Throughout 2019, the main focus of our EU Exit work was in supporting member companies in preparing for the day the UK would leave the EU. Originally planned for 29 March 2019, this was subsequently extended to 12 April and again to 31 October. At each stage, the Government accelerated its no-deal preparations, including making short-notice demands on our members.

No one could accurately predict that the UK would not actually leave the EU until 2020, therefore in a year of continued uncertainty, our top priority was ensuring appropriate contingency plans and regulatory arrangements were in place to make sure that after EU Exit, there would be no fewer OTC products available and those products would be no less safe.

PAGB's key asks throughout 2019:

 Ensure appropriate mutual recognition agreements are in place to allow over-the-counter / self care products manufactured in the UK to continue to be exported to the EU and vice versa

 Secure a simple transition process to any new arrangements, which is at least two years but ideally five years, and during which there is no divergence from EU regulation

Quantifying the impact of EU Exit

Preparation and contingency planning required PAGB members to allocate significant resources in terms of time and budgets. PAGB gathered data via quarterly surveys about members' concerns, preparations and costs, which we were able to use effectively to engage with key stakeholders.

Our ongoing relationship with health spokesperson Baroness Jolly saw the Liberal Democrats continue to highlight PAGB concerns in Parliament and on social media throughout 2019 and interest in the member survey results at the Department of Health and Social Care led to a meeting with Health Minister Baroness Blackwood in February 2019.

Snapshot from EU Exit member survey Q3, 2019

- 92%** (+18% since Q1) have 'little' or 'no confidence' in the Government's ability to obtain a 'good' deal for the consumer healthcare industry
- 58%** believe there will be fewer OTC medicines, self care devices and food supplements available in the UK if the Government fails to deliver a 'good' deal
- 67%** reported that maintaining a stockpile of medicines in preparation for 'no deal' has significantly increased the ongoing costs associated with EU Exit preparations

We made sure consumer healthcare was included in the Government's preparations.

Stakeholder engagement was an important part of PAGB's work on EU Exit in 2019. PAGB maintained open dialogue with MPs and government officials across Westminster and Whitehall; particularly civil servants from the Office for Life Sciences, who attended the PAGB EU Exit Group meeting in September to update members directly. PAGB members jointly attended meetings with stakeholders to give a company perspective on the matters raised.

The regulatory team met regularly with MHRA for both medicines and medical devices to present members' concerns and seek clarification on potential regulatory requirements on the industry. Early in 2019, PAGB raised specific concerns with MHRA over the proposed content of draft secondary legislation which was intended to enable regulation and continuity of supply in a no deal scenario. We identified that some proposals, particularly on medical devices, would cause additional burden on industry and actively worked to address these issues across all product categories.

Within food supplements, we met with DHSC to discuss the proposed common framework for nutrition across the devolved nations.

 We worked closely with other trade associations, including ABPI, ABHI and FDF, to share information and align on key regulatory issues where a collective voice would add strength to our arguments. We also worked with our European trade association, AESGP, through its Brexit Taskforce, which was chaired by PAGB Senior Director of Public Affairs and Communications, Donna Castle.

Our message to Government was clear: maximum alignment with EU regulations for OTC medicines and medical devices.

We also evaluated the potential future opportunities from EU Exit for consumer healthcare. We identified potential positive outcomes for food supplements, including amendments to the EFSA health claims and pragmatism regarding additives used in products for infants and young children. The plan is to explore these further with the Food Supplement Forum in 2020.

Future EU relationship

Throughout the summer of 2019, the attention of government officials turned to the future economic partnership between the UK and EU. PAGB met with the Department of Health and Social Care and the Office for Life Sciences to discuss our industry's priorities for medicines and medical devices regulations.

PAGB Members from the EU Exit Group, Regulatory Affairs Group and the Medical Devices Regulatory Group were involved in formulating our position including agreeing PAGB's priorities, which the PAGB team then shared with MHRA, OLS and other departments.

Following the UK General Election in November 2019 which returned a Conservative majority Government with a mandate to 'Get Brexit Done', PAGB co-ordinated a joint letter to the Secretary of State for Health and Social Care, with five other life sciences trade associations, reiterating the importance of free trade, close cooperation and regulatory alignment with the EU following the UK's departure.

We kept members regularly informed of key developments and PAGB activity.

- 182** updates posted on PAGB's EU Exit blog for members, and shared in our weekly EU Exit newsletter
- 87%** of members felt well or extremely well informed about PAGB's activity on EU Exit (PAGB member survey)



Brexit readiness

PAGB was awarded a grant by the Department of Business, Energy and Industrial Strategy to support members in preparing for a possible 'no deal' exit ahead of an expected 31 October 'exit day'. With the grant funding, PAGB reviewed the extensive government guidance available to businesses to consolidate the information of relevance to the consumer healthcare industry into one place.

We delivered two webinars on preparing for EU Exit and 'no deal' contingency planning and produced a Q&A document to address common queries from members on these issues.

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1957
PAGB convened a special committee to examine the potential for European Free Trade

CELEBRATING A CENTENARY OF CONSUMER HEALTHCARE

1919-2019

When the leaders of proprietary medicines manufacturers came together and formed our trade association in 1919, they did so because they faced challenging times and wanted to positively shape the future of the industry. 100 years later, we face different but equally challenging situations and PAGB remains a relevant and highly-respected organisation.

Our newly-curated archives are rich with examples of how PAGB members have successfully worked together demonstrating best practice in self-regulation. PAGB has supported the industry through the big regulatory and political changes of the last century, from the threat of Government regulation, the launch of the NHS and legislation to control the licensing of medicines, to new ways of advertising our products with the introduction of television and the internet.

Consumer healthcare has changed significantly in the past 100 years. Companies have grown, specialised, merged and acquired different portfolios, but the industry's aim to support people in looking after their own health remains – as do many of the enduring brands people know and trust.

Our communications strategy for PAGB's centenary was to highlight PAGB's impact in the past, its relevance today and opportunities for the future. We introduced a fresh new logo and brand identity, invigorating our member and external communications, and firmly positioning PAGB as a forward-looking organisation using the theme 'Shaping the future. Together'.

The centrepiece of our centenary celebrations was a gala event held at the iconic Science Museum on Monday 17 June 2019, exactly 100 years to the day that our founding members met to form the Association of the Manufacturers of British Proprietaries, which became the Proprietary Association of Great Britain (PAGB) in 1926.

Over three hundred guests including politicians, government officials, journalists, colleagues from other trade associations as well as staff and members, past and present gathered to celebrate PAGB's achievements. People were welcomed in 1919, dined in the present and parted into the future thanks to a carefully-themed event based on our strapline PAGB Then. Now. Tomorrow.



The story of PAGB's success was told in a video produced for the occasion by Associate Member Bray Leino providing a focal point during the event and skilfully demonstrating PAGB's impact.



Event sponsorship from Communications International Group, Precision Marketing Group, Jungle Cat Solutions and Valentis Life Sciences enabled us to put on an event that was described by guests as 'the party of the century'. A themed photo booth by Verve gave everyone a lasting record of the occasion.



Our centenary provided an opportunity to speak out about PAGB and its plans for the future.

A special PAGB centenary supplement in trade magazine, HBW Insight highlighted PAGB's impact in self-regulation and its effectiveness as the voice of the industry on regulatory and self care issues.



PAGB's monthly Spotlight newsletter featured a series of in-depth features from members and stakeholders looking back on the impact of PAGB and sharing predictions for the future of consumer healthcare. Guests included Alliance Pharmaceuticals, makers of Ashton & Parsons teething powder, one of the first products in PAGB membership and the British Medical Association, whose publication 'Secret Remedies' in 1914 led to calls for regulation of the medicines industry, and therefore was a significant factor in the foundation of this association. Also featured were MHRA, ASA, Royal Pharmaceutical Society, AESGP and the Global Self Care Federation.



Chief Executive, John Smith accepting PAGB's Lifetime Achievement Award at the 2019 Consumer Healthcare Industry (CHI) Awards.



Strengthening the case for self care



In January 2019, NHS England published its Long Term Plan for the National Health Service, an ambitious 10 year strategy signalling a renewed focus on prevention and helping people to stay healthy, with a view to ensuring the future sustainability of the service.

While there was much to welcome in the new plan, PAGB felt that the omission of clear policies to support a behavioural shift towards self care was a missed opportunity.

In response, PAGB published a Self Care White Paper setting out policies which, if implemented, would support the delivery of the Long Term Plan and release savings of £1.5 billion back into the system.

Of the recommendations in the White Paper, we prioritised three which would deliver a step-change in self care:

- The introduction of recommendation prescriptions to enable GPs to refer people to self care, or to the pharmacy for advice
- Referral from pharmacy to other healthcare professionals, fast-tracked if necessary
- Pharmacists to have the ability to 'write' to people's medical records.

These recommendations formed the basis of discussions with policymakers and stakeholders across the healthcare sector, enabling us to demonstrate where self care could help reduce pressure on primary care, and enhance the role of pharmacists, in line with NHS thinking.

Meetings included with officials from the Department of Health and Social Care and NHS England, colleagues from the pharmacy organisations, NHS Clinical Commissioners, the Dispensing Doctors' Association and the Patients Association.

In 2019 PAGB provided an industry response to nine consultations, including the Government's Prevention Green Paper and National Food Strategy on behalf of members.

Establishing clinical consensus

To deliver effective self care policies requires alignment across the health sector. In October, we convened a roundtable meeting of healthcare professionals in Parliament to discuss the role of self care in the future of the NHS. Chaired by Sir George Howarth MP, attendees included the Royal College of GPs, pharmacy organisations, NHS Clinical Commissioners and NHS England. Sir George subsequently sent a report of the meeting to Health Secretary Matt Hancock, lending his full support to our recommendations.

Self care and technology

The NHS, under Health Secretary Matt Hancock, is exploring the potential for digital transformation to accelerate integration and improve outcomes. In 2019, PAGB published a paper: *Self care and technology: Harnessing the potential of technology to transform self care*, looking at how digital technology could be utilised to empower more people to self care.

PAGB member companies helped to identify case studies from around the world, showing the ways that digital technology has the potential to improve signposting to self care and provide people with information about self-treatable conditions.

The report's recommendations are largely directed at NHSX, NHS Digital and NHS England, and include:

-  A dedicated self care section in NHS health information sources, including the NHS app
-  existing apps and wearables to support greater self care, including signposting to pharmacy
-  pharmacist advice and digital access to the OTC directory to be included in Primary Care IT systems
-  pharmacists to have "write" access to patient health records

The report had a positive reception from stakeholders, including the Department of Health and Social Care, NHSX and NHS Clinical Commissioners. We will continue to pursue these recommendations through PAGB's digital workstream in our strategy to 2025.

5 pieces of media coverage were secured in target trade press titles.

Working with Associate Member company IPSOS Mori, we shared the recommendations from our Self Care and Technology report in a webinar on the Future of Self Care during Self Care Week.

Overcoming barriers to self care

To mark Self Care Week in November, PAGB published an analysis of the barriers to implementation for our three priority asks, with recommendations for overcoming these concerns and case studies of successful implementation of self care policies.

Read our reports at <https://www.pagb.co.uk/policy/research-and-reports/>



Supporting healthcare professionals to recommend self care

In 2019, we published a new edition of PAGB's OTC Directory. Since 1993, this guide to branded self care products has been used by GPs and other healthcare professionals to help them support people to self care for self-treatable conditions.

The 2019 edition of the Directory was sent to a total of 59,000 healthcare professionals including over 36,000 GPs who also received a pad of recommendation prescription forms, developed in partnership with member company RB. GPs responded very positively to receiving the recommendation prescriptions and PAGB is collecting data to support our call for this to be implemented across the NHS.

Research we conducted with GPs found that:

76% of GPs think having the OTC Directory available online would be fairly or very useful

73% think it would be fairly or very useful in online prescribing systems

51% think it would be fairly or very useful in print

The PAGB Board decided not to reprint the directory in 2020 and to focus future investment on optimising access to the OTC Directory online to ensure this continues to be of value to healthcare professionals.



1980

PAGB published pioneering work on the economics of self-medication

Media engagement

PAGB supports its members on media engagement in response to issues relating to consumer healthcare products and self care. As the voice of the industry, we can respond to issues on behalf of all members, providing balance to stories which could otherwise adversely affect consumer confidence in the safety or efficacy of OTC products.

In 2019 PAGB received fewer media enquiries overall than the previous year, but on a much wider range of medicines and medical devices issues.

Pain relief remained the most common topic, followed by the prices of branded and generic medicines, but there were fewer requests on each. New issues emerged in 2019 including on ranitidine, weight-loss products and the salt content of effervescent products.

Media coverage 2019



In 2019 PAGB worked with GP, Dr Sarah Jarvis and pharmacist, Deborah Evans to agree expert statements for use in response to media issues.



These healthcare professionals also contributed to proactive media activity in support of PAGB's self care campaigns.

A voice of balance on food supplements

PAGB funds the Health and Food Supplements Information Service (HSIS) to respond to media enquiries about nutrition and food supplements.



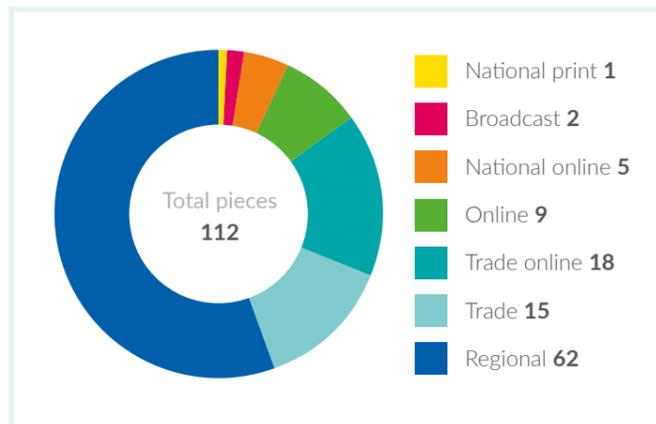
Dr Chris Etheridge explains: "During 2019, the media was most interested in omega-3s and vitamin D. There is a lot of research being carried out in these areas at the moment, much of which provides us with more questions than it does answers. It is important for HSIS to help journalists sort the facts from the fiction and ensure media stories include accurate and balanced information about nutrition and the role of food supplements".

90% of HSIS coverage included an HSIS quote

70% of coverage appeared in tier 1 publications vs KPI of 50%

More about HSIS on page 22.

Where our coverage appeared in 2019

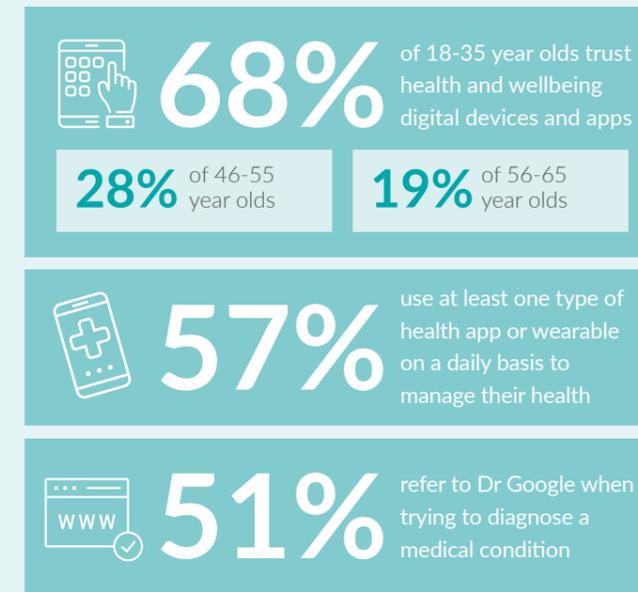


Promoting self care in the media

We launched PAGB's Self Care White Paper to the media in March 2019. We chose to lead with our recommendation for self care to be included in the school curriculum to empower future generations to self care for self-treatable conditions, helping reduce demand on NHS services. This generated 56 pieces of coverage.



We also achieved media coverage for our self care campaigns on the role of technology in the future of self care and on the barriers to self care (see page 18). We included findings from research we commissioned with healthcare professionals and consumers to support the key messages, for example on the rise of digital healthcare:



PAGB's centenary was an opportunity to talk proactively to the media about PAGB and the importance of what we do.



A piece authored by GP, Dr Sarah Jarvis, on the importance of self care was published by the Huffington Post to coincide with PAGB's centenary in June 2019.

The centenary also presented opportunities with our target trade media.

PAGB President, Neil Lister, gave interviews to P3 Pharmacy magazine, Independent Community Pharmacist magazine and HBW Insight.



HBW Insight

Informa Pharma Intelligence

A four-part interview with Chief Executive, John Smith was published in HBW Insight.



News of Michelle Riddalls' appointment was picked up by five target trade titles and following her appointment, she gave an interview on reclassification to HBW Insight.

100 years **PAGB**

1924

First advice to the press on misleading advertising claims made by non-members

20 years of HSIS

2019 was also a milestone year for the Health and Food Supplements Information Service (HSIS), which celebrated twenty years of providing accurate and balanced information on nutrition and food supplements issues to the UK media.

To mark this anniversary, HSIS produced an important new piece of research, produced by HSIS expert Dr Emma Derbyshire, which was published in the Journal of Vitamins and Minerals in July 2019. This peer-reviewed research was based on an analysis of data from the Government's National Diet and Nutrition Survey Rolling Programme, and DEFRA's family food surveys. It showed a marked decline in the intake of important dietary nutrients across all life stages and detailed deficiencies by age group and gender.



HSIS produced an accompanying report, 'State of the Nation, dietary trends in the UK 20 years on', expanding on the findings, as well as supportive materials including infographics to deliver the information in an engaging way to journalists and their readers. The result was a sustained and impressive amount of coverage in national newspapers and consumer media which covered the report's findings and the role of food supplements in supporting health to address nutrient gaps.



- 35** journalists attended a private media lunch to learn about the findings from HSIS experts
- 3** exclusives
- 34** articles generated
- 20** one-to-one media briefings secured
- 9** pieces in the national media
- 1** in Tier 1 target publications
- 60%** of pieces included at least one key message



Dr Emma Derbyshire presents the HSIS report to journalists



Vegetarian and vegan diets

In 2019, HSIS ran a media campaign to educate people choosing a vegetarian diet on the specific dietary gaps to watch out for. Consumer research with 1,000 vegetarian and vegan adults found a worrying lack of knowledge about how to obtain adequate nutrient intakes when following a vegan or vegetarian diet.

60 per cent of people admitted that they had done no research before cutting out animal products and most did not take a targeted dietary supplement, as recommended by the NHS and the Vegan Society.

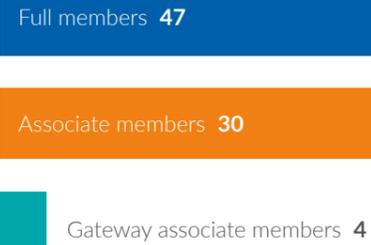
HSIS has seen ongoing interest in this issue with regular coverage in national and consumer titles.

HSIS was established in 1999 as a communications service to help educate those writing about nutrition issues in the media. It is funded entirely by PAGB but the views of its authors and experts are their own. This editorial integrity has been an important part of HSIS's success as has the dedication of the HSIS press office, which is managed by specialist communications agency Jungle Cat Solutions.

In robustly defending against misrepresentation and providing much needed balance to the debate on the value of supplementation, HSIS has had an important impact on the way that food supplements are discussed in the media.

Membership

Membership at 31 December 2019



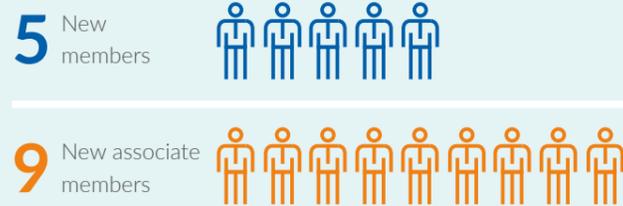
New member companies came predominantly from new entrants to the industry, particularly in the field of medical devices and food supplements. We saw a net decrease of two associate members in 2019, despite accepting nine new companies into associate membership.

We encourage members to consider PAGB associate members when looking for a new supplier so we were pleased to hear that new members had been recommended to join PAGB by current members.

Respondents to PAGB's member survey gave a net promoter score of 48 ('great') on the question **'How likely are you to recommend PAGB membership to new entrants in the industry?'**

At its September meeting, the PAGB Board gave the go ahead for a new Membership and Communications Executive to join the PAGB team. This role, from January 2020, will enable PAGB to focus more on the value of PAGB membership and on recruiting new companies into membership to strengthen the association.

New PAGB members in 2019



Events and training to upskill the industry



We introduced new members to PAGB at welcome events in February and November, giving an overview of PAGB services and providing information on how to make the most of membership. New members and people new to existing member companies were able to network with each other and with PAGB Board members.

Keeping members up to date



(PAGB member survey, see page 26)

Our newsletters continue to be a popular resource for members with consistently above average engagement rates.



Opportunities for associate members

- Associate members wrote articles that appeared in PAGB member newsletters and online.
- Through the Associate Member Working Group, associate members contributed their unique perspective to PAGB's strategy development discussions and advertising guideline reviews.
- In 2019, PAGB made an important change to its approach to working groups, for the first time enabling groups to invite associate members to join and contribute their expertise.



Financial position

PAGB is largely funded by subscription fees paid by member and associate member companies. We carefully manage our expenditure to enable us to provide our core services to members and ensure that our income is used responsibly.

In 2019, thanks to careful financial management, we ended the year with a small profit at +£600, against an agreed deficit budget of -£61k.

We were able to deliver this despite a lower-than-inflation average member fee increase of 2.1 per cent. This is partly thanks to income from attracting new associate member companies into membership. Our aim is to continue seeking alternative revenue sources such as growing training revenue and widening our membership.



Significant areas of income and expenditure in 2019 included a special EU Exit readiness project (funded by a grant from the Department for Business, Energy and Industrial Strategy); ingredient issues projects (additional contributions from relevant members); and our centenary celebrations (funded through ticket sales and sponsorship).

100 years
PAGB

1972

PAGB welcomed its first associate members

Member survey results

Our annual survey of PAGB Member companies showed confidence in the leadership at PAGB and high satisfaction across all member services.



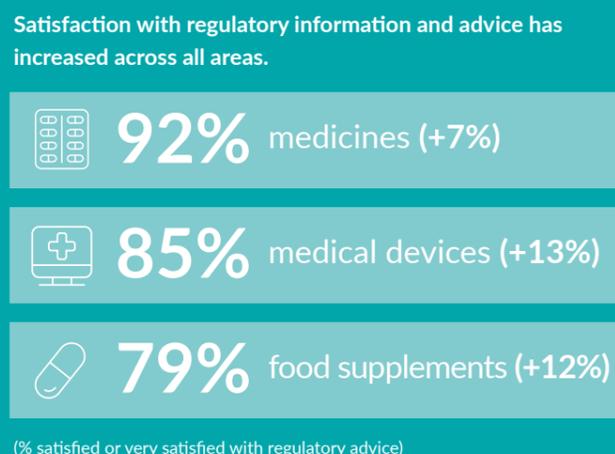
We were encouraged by another excellent return rate for the survey – around two-thirds of member companies submitted responses, and like last year, these were informed by senior management teams gathering feedback from across their companies to give a comprehensive company response.

Our thanks to PAGB associate member, Verve, for supporting the production and analysis of this survey.

“As a new member and new market entrant with innovative products, having the support of PAGB has made a big difference.”

“Exceptional communication for an organisation”

“Good to see strong Regulatory Affairs leadership.”



Members continue to be pleased with PAGB support through the EU Exit process and report confidence in our influencing ability



“This is an area where PAGB has shone and shown its ability to co-ordinate and inform the industry of highly important issues.”

PAGB has been working to address concerns about consistency and speed of copy advice, by implementing a new approvals system with optimised precedent-searching to give assessors more tools to support members. This is a significant project, and the benefits will be seen over a longer period but already there are signs that this is improving members' experience of the copy approvals process.

Increase in satisfaction with medicine copy advice:



“For a small independent supplier the support we had from copy clearance was crucial to be able to develop our new brands and product range and has given us the confidence now to approach the market knowing we are compliant.”

“Recent improvements have been made and consistency has improved.”

We saw an uplift in satisfaction with PAGB's self care activity which can be partly attributed to better communicating this to members – something we recognised needed improvement as a result of the 2018 survey.



“We are confident that PAGB's policy-influencing strategies and multiyear plans are well thought through, relevant and have the ability to deliver real impact.”





As a trade association, it's important that PAGB represents the interest of its members and the wider consumer healthcare industry.



Our members are at the centre of what we do, and how we deliver it.

Participation in working groups gives PAGB members the opportunity to directly influence and contribute to activity that will enable us to achieve our strategic goals. Thank you to all group members for your contribution in 2019.

Members on PAGB working groups are also given regular opportunities to accompany PAGB staff to meetings with regulators and government officials. In doing so they represent the wider membership and give an important industry perspective on discussions. In 2019, members joined us in meetings on EU Exit, medicines and devices regulation, and self care policy.

PAGB's Board sets the strategic direction and work programme for PAGB. It is made up of representatives from fifteen member companies.

Alliance Pharmaceuticals Ltd
Bayer PLC (Vice-president)
Ceuta Healthcare Limited
DDD Ltd
G R Lane Health Products Ltd
GSK (Vice-president)
Infirst Healthcare Ltd
Johnson and Johnson
The Mentholatum Company Limited
P&G Health
Perrigo (President)
Pfizer Consumer Healthcare Ltd
RB UK Commercial Ltd
Sanofi
Thornton & Ross Ltd
Honorary Treasurer, Bron Gorny

Regulatory Affairs Group

Reclassification sub-group

Pack Design sub-group

PIE sub-group (new 2020)

EU Exit sub-group (new 2020)

Regulatory issues and challenges; relationship with MHRA and key stakeholders; EU Exit

Medical Devices Regulatory Group

EU Exit sub-group (new 2020)

Medical devices issues including implementation of the Medical Devices Regulation

Food Supplements Forum

CBD sub-group (new 2020)

Survey and Guidance Update (new 2020)

EU Exit sub-group (new 2020)

Food and nutrition regulation updates and issues

EU Exit Group

PAGB policy priorities for EU Exit; stakeholder engagement

Digital Working Group (new in 2020)

Advertising sub-group

Apps sub-group

E-commerce sub-group

Self Care sub-group

Patient Information sub-group (deprioritised)

Identify and create opportunities for consumer healthcare related to digital

Public Affairs and Communications Group

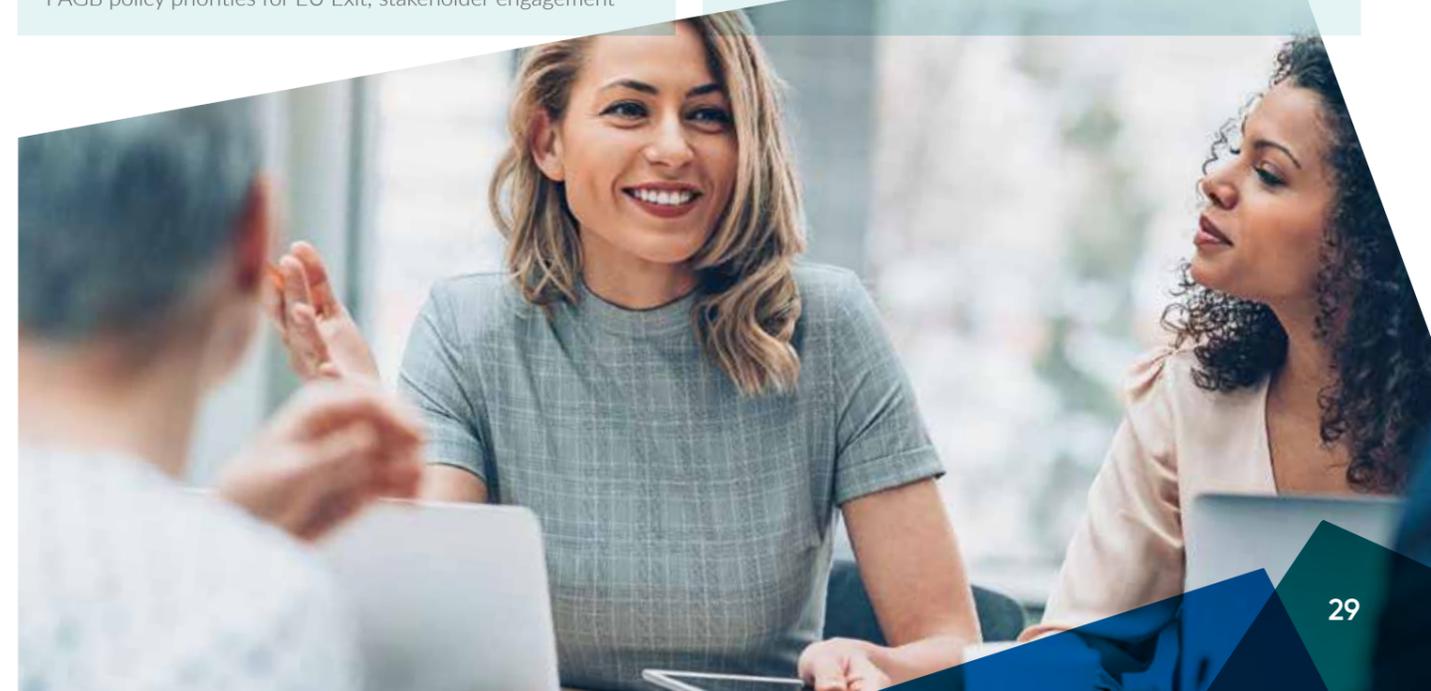
Policy development, self care campaigns, media issues; HSIS

Advertising Working Group

Update PAGB codes and guidance; changes to copy clearance service

Associate Member Working Group

Receive updates on PAGB strategy and workstreams; Associate member perspective on PAGB services



PAGB members at December 2019



PAGB associate members at December 2019



100 years
PAGB

1919

The first fifteen companies were admitted into membership of the Association of Manufacturers of British Proprietaries (which became PAGB)

Who we are and how to get in touch

PAGB Management team

Strategic oversight; key stakeholder engagement; EU Exit; representing PAGB on national and international bodies.



Chief Executive
John Smith
john.smith@pagb.co.uk



Senior Director of Public Affairs and Communications
Donna Castle
donna.castle@pagb.co.uk



Senior Director of Regulatory Affairs and Advertising Services
Michelle Riddalls
michelle.riddalls@pagb.co.uk

Advertising Services

Copy advice and approvals; workshops; compliance; PAGB Codes and guidance.



Advertising Services Manager
Laura Kelly



Codes of Practice Assessor
Jenny Capel



Codes of Practice Assessor
Francesca Cappozzo



Codes of Practice Assessor
Henry Hodgson



Codes of Practice Assessor
Florence Taylor



Advertising Services Administrator
Amy Finnegan

copyclearance@pagb.co.uk

advertisingadmin@pagb.co.uk

Regulatory Affairs

Advice on regulation relating to OTC medicines, medical devices and food supplements; pack design review for medicines; regulatory engagement; ingredients issues.



Senior Regulatory Executive (Medical Devices)
Christina Gkouva



Senior Regulatory Executive (Food Supplements)
Victoria Trowse



Regulatory Executive (OTC Medicines)
Femi Omotade

regulatory@pagb.co.uk
foodsupplements@pagb.co.uk

Public Affairs & Communications

Self care campaigns; media relations; public affairs; policy positions; member communications; PAGB website; publications; OTC Directory; membership.



Senior Communications Manager
Nikki Kennedy



Media and Communications Manager
Polly Newton



Membership and Communications Executive
Maryrose Okere

policy@pagb.co.uk
media@pagb.co.uk
website@pagb.co.uk
membership@pagb.co.uk

Operations & Administration

Administrative and operational support for PAGB and its members; accounts; room bookings; HR.



Finance and Facilities manager
Lorraine Lee



HR and Administration Manager
Pauline Young

info@pagb.co.uk
events@pagb.co.uk
accounts@pagb.co.uk



1926

The Association of Manufacturers of British Proprietaries changed its name to Proprietary Association of Great Britain



Shaping the future.
Together.

PAGB, the consumer healthcare association

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100 years
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