

# **EMBRACING** CHANGE

Annual Review 2017-18

Representing the Consumer Healthcare Industry since 1919

### Are you getting the most out of your membership?

Copy clearance and pre-campaign advice copyclearance@pagb.co.uk

**Regulatory support on medicines** and self care medical devices regulatory@pagb.co.uk

Regulatory support on food supplements tccallis@pagb.co.uk

Member-only news, information and resources www.pagb.co.uk/members-area

Training, events and seminars events@pagb.co.uk

Room hire and hotdesking info@pagb.co.uk

Campaigns to promote self care selfcare@pagb.co.uk

PAGB support on media issues and campaigns media@pagb.co.uk

Policy, public affairs and stakeholder engagement policy@pagb.co.uk

"The benefit of PAGB membership is felt across our consumer healthcare business. Our whole team can benefit from regular updates and training as well as opportunities to directly influence PAGB policy through its working groups.

We regularly call on PAGB's expertise in advertising, regulation and self care to help ensure that we're at the top of our game."

Neil Lister, Vice President International and Managing Director UK & Ireland, Perrigo **PAGB Vice-President** 



Did you know that all UK employees in your consumer healthcare business can subscribe to our newsletters? We encourage everyone to sign up www.pagb.co.uk/members-area/member-comms



The voice of the industry on EU Exit

18

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Making the case for self care

Introduction: A year to embrace change The consumer healthcare market Making progress on our strategy **PAGB** finances Inside PAGB: our membership Training and events PAGB advertising services Feature: Supporting innovation in advertising **Regulatory Affairs** Feature: A change in Primary Authority Representing the industry on EU Exit Highlights from our EU Exit programme Managing media issues Promoting self care policy Feature: NHS England prescribing guidance Our self care campaigns A report from the Self Care Forum PAGB working groups **Our Members Our Associate Members** Meet the team



A new claim for food supplements

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A year to embrace change

The last year has been one of change for PAGB, both internally and externally.



We have created opportunities to speak out on policy issues including EU Exit, NHS prescribing and self care as the external environment continued to shift.

We worked closely with Members to understand their priorities, adapting our work programme to direct more resource into the areas where we can have the greatest impact. On the regulatory side, we were delighted to see an increase in the number of successful reclassification applications, increasing access to effective medicines over-the-counter.

Our work with the Medicines and Healthcare products Regulatory Agency (MHRA) on reclassifications is just one area where we have seen the benefit of building a good relationship with the medicines regulator.

products were successfully switched between 1 July 2017 and 30 June this year. Uncertainty around the UK's withdrawal from the EU remains. In November 2017, we formed a Member working group to monitor developments and inform PAGB's response. As part of our stakeholder engagement programme we have secured meetings with senior officials in Government to ensure our concerns are being taken into consideration.

### More information about our response to EU Exit is on page 18.

The growing pressure on the NHS has continued to be a key driver for healthcare policy, which has enabled us to talk to politicians and policy makers about the benefits of self care. Most notable among these is the NHS England consultation and resulting guidance on the prescribing of OTC products for self-treatable conditions, which prompted debate over the role of self care in the NHS.

PAGB's response called for a national strategy for self care and a system-wide approach to fully support the necessary behaviour change.

Read more about our response to the consultation on page 26.

It has been a year of closer collaboration with external partners. We continued our partnership with Public Health England and NHS England on the Stay Well This Winter campaign and extended the message by partnering on the new Stay Well Pharmacy campaign which launched in February 2018.

Working with the Self Care Forum and the Royal College of General Practitioners (RCGP), we took our shared messages to policy makers with an infographic about how self care can save time and reduce demand in primary care.

We've experienced change internally too. We moved into new offices in October 2017, which offer better facilities for staff and a more modern working space. We invite Members to make use of our two meeting rooms and hot desk area. We have been working on improving our internal processes and procedures in response to new data protection legislation, and to ensure our work is as streamlined as possible. Work has also begun on a new case management and contact management database which will enable us to more efficiently provide advertising advice to Members.



#### We continue to strive to provide a world class service to our Members.

Our copy clearance team has worked exceptionally hard to clear 9,285 pieces of copy despite staff changes and vacancies in the team.

We also started a review of the PAGB Consumer Code for Medicines to ensure that it reflects current advertising rules and continues to support effective self-regulation.

We would like to thank PAGB staff for their dedication and hard work over the last year and our colleagues in Member companies who have attended meetings, contributed to working groups and supported projects over the last year of change. Several new Members joined the PAGB Board in the last year and while thanking their predecessors for their contributions we look forward to working with our new colleagues to deliver the PAGB strategy.

As we plan ahead to our centenary year in 2019, we will continue to embrace change and look forward to the next 100 years of effective self-regulation.



John Smith PAGB Chief Executive



David Barnett PAGB President

This year has been a positive one for consumer healthcare, and a marked step change from last year. The OTC market is not only feeling relief after last year's slowdown, but is showing signs of a full recovery as we see value increases of 3.7% alongside a 1.5% increase in volume across all categories.

The biggest drivers for this are down to inflationary price increases which, as a knock on effect, have prompted shoppers to trade up in the category.

People have also bought more OTC products thanks in part to a prolonged cold and flu season at the back end of last year, and an intense hayfever season that came along with this year's early spring and hot summer.

Last year, the biggest declines in the OTC market came from the more commoditised segments such as analgesics and cold relief. This is not the case this year, where most of the growth has come from those exact segments that were pulling the overall category down last year.

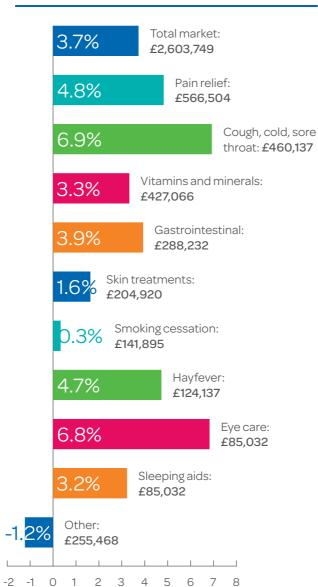
The cough, cold and sore throat segment was, in fact, the fastest growing at +6.9% in value and +2.7% in units, thanks to a strong season with prolonged cold weather and higher average product prices. Strong growth also came through in pain relief with a 4.8% increase in value and 3.1% increase in volume, with paediatric analgesics up a big +10.5% in value compared with last year.

Vitamins and minerals also came through strongly this year with value growing at 3.3% ahead of units growing at 0.9%, driven primarily from own label as the biggest player in the category. The segment to see the highest average price increases, gastrointestinal at +8.1%, achieved a 3.9% growth but a decline of 2.4% in volume, a dynamic we see across the top brands where price increases are stimulating the value growth.

While this year paints a much more positive picture than the last, it still reinforces the importance of seasonality as the key to unlocking growth in OTC. Well-planned, strategic promotions continue to be essential to maximise continued growth across the category and manufacturers and retailers will need to keep a sharp focus here amidst promotional budgets that remain under pressure.

Vitaliy Zhyhun, Nielsen Commercial Business Partner

#### % change in value sales of OTC products (£000) (July 2017 to July 2018)



We're halfway through our 2017-2019 strategy and making good progress against the annual targets we set ourselves for 2017 and 2018, across all four strategic pillars.

> We will be recognised by our stakeholders for shaping the UK consumer healthcare market



Our team feels valued, is engaged and has a sense of purpose and accomplishment

Good governance & a strong financial position

We've also strengthened our foundations with good financial management and a review of our governance procedures.

### nielsen

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.



#### 2017 financial position (£000s)

Income: 2,254

Expenditure: 2,177

2017's finances paint a broadly similar picture to 2016. This year's annual income was slightly higher, principally owing to Member subscriptions up 2% and increased attendance at workshops.

#### Workshop revenue + 35% in 2017

Expenditure was similar to the previous year resulting in a larger profit, which has been allocated to our reserves.

The move to our new offices has enabled PAGB to cleanse the balance sheet of old fixed assets, mostly fully depreciated.

We began 2018 in a healthier financial position: our reserves now represent approximately four months of annual costs. This will be reviewed in 2018.

PAGB is funded by subscription fees paid by Member and Associate Member companies. Expenditure is carefully allocated to enable us to provide our core services.

## Expenditure by function (2017) Advertising services: 23% Admin/finance: 18% Communications: 24% Public affairs: 17%

#### Membership in numbers (year to 30 June 2018)

48

63%

0

+77

of the market (value)

of the top 50 consumer healthcare brands

**PAGB** Members manufacture and/or market branded non-prescription medicines, self care medical devices, food supplements or registered herbal medicines in the United Kingdom.



#### **New PAGB Members**

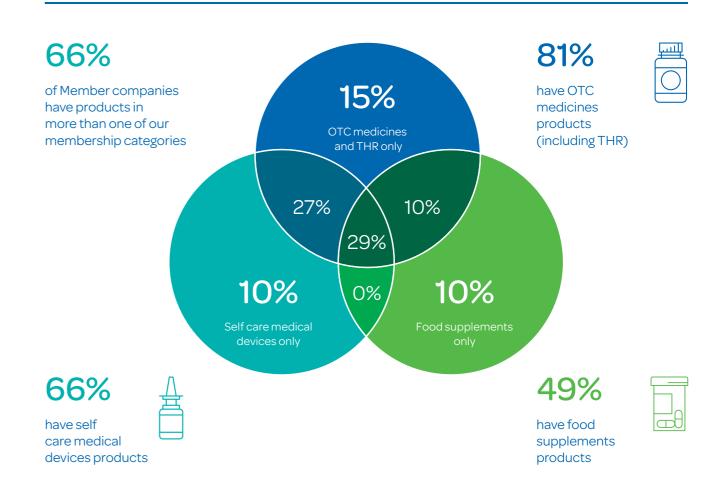
0 0 0  $\mathbf{O}$ 4 New Members

5

New



#### PAGB Member companies by type of products in membership





#### **Our Associate Members are** companies that provide, or could provide, services to Member companies.

Joining PAGB demonstrates their commitment to the consumer healthcare industry and gives them access to information to keep them up to date on Members' priorities. It also means that they can access PAGB advertising and regulatory services on behalf of Members.

We're working to widen our Associate Membership to build a growing pool of suppliers who really understand how to support the consumer healthcare industry.

"Working with an Associate Member of PAGB has really helped make the approval process of our campaign messages smoother. We greatly appreciate the support received and the quick turnaround from PAGB which has been a crucial element in the success of the Maloff Protect campaign."

Glenmark, working with Hamell Communications

PAGB training on its Consumer and Professional Codes for Medicines provides an essential grounding in the application of the Codes and accompanying guidance.

In March 2018 we presented the first of our restructured and refreshed medicines advertising workshops.

New examples and an interactive element have helped bring the workshops up to date.

We also delivered bespoke and private courses, tailored to specific areas of the advertising codes, giving companies the opportunity to understand how to ensure their campaigns are compliant.

- ✓ Popular with new starters or movers
- Can be delivered to whole teams on request
- Member discount on our standard workshops



"We regularly send people from our consumer health team on PAGB training workshops. The training is so valuable, we asked the team to come and train our field sales staff on the PAGB Professional Code for Medicines."

Cristina Bassi, Regulatory Affairs Director Health, RB

PAGB workshops remain popular with Members and non-members.

22

workshops delivered

214

total attendees at PAGB workshops



of attendees were Members and Associate Members



came from nonmember companies



The PAGB Professional Learning Programme is a series of training modules that can be combined to achieve the PAGB Diploma in OTC Healthcare.

It's a great progression for people who have attended our workshops.

learners signed up to study on the Professional Learning Programme

completed the PAGB Diploma in OTC Healthcare

In 2018 we began moving the Professional Learning Programme onto a new interactive platform.

Watch this space...

PAGB organised two exclusive member seminars: on EU Exit with MHRA and on gender stereotypes in advertising, with CAP/ASA.

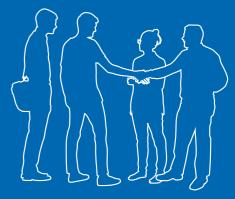


At the gender stereotypes in advertising seminar (January 2018), Members and Associate Members heard about the proposed new rules directly from CAP project lead, Ella Smilie and could ask questions about its implications for their campaigns.

### "PAGB has supported CAP/

ASA's work on depictions of gender stereotypes in advertising. PAGB's seminar was a great opportunity to engage directly with advertisers and agencies on the potential implications for consumer healthcare advertising. We welcome PAGB's support to tackle harmful gender stereotypes in advertising."

Ella Smillie, gender stereotyping project lead, Committees of Advertising Practice



Our Meet and Mingle event in December gave Members and Associate Members an opportunity to network with key stakeholders and each other.

### Copy clearance and so much more.

Year to 30 June 2018

We assessed

9285

pieces of copy

61

per assessor, per week



#### We ran 13 workshops

Now refreshed and more interactive

10 OTC medicines advertising

3 Food supplements = 8



We delivered

9 bespoke and private training seminars

We presented

the year in advertising at MHRA's 'Hot Topics' webinar in March 2018



449 online, so 219

> in sto 7%

> > prir



#### We responded to

#### 1113

requests for advertising advice from Members and Associate Members



#### We met with company brand teams

to discuss campaign challenges and offer solutions

10

#### Wesaw an increase

in submissions of online and social media content

#### We reviewed a wider variety of materials

<mark>%</mark>	6%
ocial, VR	radic
<mark>%</mark>	<b>6%</b>
ore	00H
<b>6</b>	<b>16%</b>
nt	othe

#### We considered

tricky cases as a team

While Members know the importance of PAGB approval, the team offers more than just a stamp.



Laura Kelly, PAGB's Advertising Services Manager, presents some highlights from the last year.

#### She shows how PAGB has enabled our Members and their creative teams to produce innovative campaigns that work within the PAGB code.

We're always excited to meet with creative teams to ensure they start off on the right foot, and this is never more important than when a brand is launching a new project.

We've seen some great creative ideas this year and helped bring them to life in a way that's compliant and responsible.



"PAGB has helped us to create unique, world-first campaigns for Sudocrem. We recently used Facebook Live to produce one of our most successful campaigns, in terms of engagement, to date. PAGB worked with us every step of the way and the results have been amazing.

It's often a tricky line to walk in terms of digital, especially for licensed medicines however with PAGB's help we have been able to produce some extremely engaging and fun campaigns that the social communities love."

PAGB Associate Member Orbital Media reflects on its campaign for Sudocrem (Teva UK Limited)



#### ellaOne, HRA Pharma Connecting with consumers through social media

ellaOne launched a cross-media campaign, tying together a new TV ad with social media to really connect with its target audience of 18-24 year old women. PAGB worked closely with HRA Pharma on concept development.

#### Key to effectively reviewing and approving the campaign was ensuring that we thoroughly understood the brand's mission and messaging.

We held meetings and explored ideas together enabling the ellaOne team to check out its ideas before committing to them. The aim was simple: to reduce embarrassment around buying emergency contraception.

The e-commerce 'click and collect' feature together with an online pharmacist consultation meant that women could simply pick up the product in store. The ellaOne team was able to communicate this message directly in conversation with the consumer on social media.

With limitations on content size and the need to respond quickly in social conversations, marketers often worry that keeping campaigns compliant is difficult or obstructive. ellaOne showed that this isn't the case; through thoughtful planning, ellaOne reached its target audience with a coherent and compliant message that joined up across media.

In the coming year we'll be looking to apply what we've learnt to help modernise our guidance and processes, ensuring that PAGB can continue to support member innovation as creative teams develop exciting new campaigns. Nicorette's My Quit Plan, Johnson & Johnson Ltd Augmenting the reality of quitting

The Nicorette marketing team created a campaign that used a range of interactive online tools, each presenting unique challenges.

My Quit Plan offered consumers 24/7 support through an advice website and Facebook Messenger Chatbot.

PAGB's Copy Clearance team approved wording for the advisory chatbot, making sure that the conversation could flow naturally while remaining compliant with the PAGB Consumer Code and Social Media Guidance.

We also approved all website copy and ensured that testimonials were in line with the PAGB rules while reflecting the real-life experiences of consumers.

Nicorette brought one of the inspirational stories to life at Kings Cross station, offering commuters the chance to experience slacklining, a form of tightrope walking, through augmented reality.

From approving the concept to reviewing footage of the day, the copy clearance team ensured that Nicorette could confidently use its campaign content across social media. PAGB provides specialist regulatory advice to our Members on OTC medicines, self care medical devices and food supplements.

It was another good year for increasing access to medicines.

13

7

products were reclassified (1 July 2017 – 30 June 2018)

were major reclassifications i.e. first in new therapeutic category or new target population

Major reclassifications (1 July 2017 – 30 June 2018)

6

POM to P

1 P to GSL

PAGB supported Members in preparing for the launch of newly reclassified products, including advertising support post-reclassification.

> Viagra Connect became the first product available over-thecounter for erectile dysfunction



#### Our relationship with MHRA

In addition to our bilateral meeting in December 2017, we attended regular meetings to provide input from industry and worked closely with MHRA on ingredients issues.

- Medicines, Medical Devices and Advertising Industry Liaison Groups (MILG, MDILG and MALG)
- GMP GDP Consultative Committee
- MHRA CAP Borderlines Group
- EU Device Regulations External Strategy Group (EESG)
- MHRA Cross-Trade Deep Dive

### MHRA also attended and spoke at meetings organised by PAGB.

- EU Exit Seminar, November 2017
- Medical Devices Regulatory Group December 2017 and June 2018
- Regulatory Affairs Group June 2018

#### Supporting expedited pack review

47 Member companies and 6 non-members submitted packaging to our medicines pack design review service which enables expedited approval from MHRA.

#### The Regulatory Affairs Group

The Regulatory Affairs Group (RAG) provided regulatory insight and technical information to support PAGB's objectives.

In 2018, priority issues for the RAG were:

- 🗸 EU Exit
- $\checkmark$  reclassification
- ✓ ingredient issues
- ✓ pack code review

#### Read more on page 33.

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Single-use plastics became a big issue in 2018.

PAGB worked with Member companies to clarify the industry position on the use of plastics for medicines, self care medical devices and food supplements products.

Together with other trade associations, we're working to avoid unintended consequences from this environmental policy.

PAGB submitted a response to HM Treasury's call for evidence on plastics.



We kept Members up to date with the latest UK and EU regulatory news via Regulatory Intelligence, our weekly e-newsletter and online at pagb.co.uk/ regulatory-resources.





PAGB continues to actively engage with the Advertising Standards Authority and the Committees of Advertising Practice on advertising regulation.



In August 2017 we visited CAP and the ASA to give a presentation on PAGB's history and services.

PAGB attended 6 Committees of Advertising Practice meetings.

As a member of CAP's Gender Stereotypes Working Group, we contributed to the development of a proposed new rule and guidance on gender stereotypes. Including a pre-consultation workshop run by CAP in January 2018.

### "PAGB has long had a voice at the advertising self-regulatory table.

Through its membership of CAP, PAGB represents the interests of OTC businesses and raises issues and concerns that feed directly into shaping how the rules are developed. It is a member of our stakeholder engagement programme, which helps improve our lines of communication, provides a direct point of contact and bolsters understanding and knowledge sharing between us so we can address problems quickly and effectively.

And finally, PAGB is blessed with a first class approval system of its own for its members' consumer advertising, helping to spot potential problems before they appear in ads."

Guy Parker, Chief Executive, ASA

**Primary Authority** 

### A new partnership gives health claims a boost.



TC Callis, Food Supplements Regulatory Manager explains how PAGB is supporting Members to use health claims more flexibly.

#### Ground-breaking advice

Changes to PAGB's Primary Authority partnership in 2017 led to us securing a ground-breaking piece of Primary Authority Advice (PAA) that allows Members to use the term "antioxidant" as an Article 10 general health claim if it is accompanied by an appropriate authorised claim.

Previously its use was only allowed as explanatory text within the context of a health claim.

The new advice gives PAGB Members who are part of the new coordinated partnership greater flexibility in how they describe food supplement products in marketing campaigns. This is unique to our Primary Authority at the time of writing. After entering a Primary Authority partnership with Cambridge and Peterborough Trading Standards in October 2017, PAGB immediately sought a review of its existing advice on the use of the terms 'scientifically proven' and 'antioxidant'.

> Our existing advice on the term 'scientifically proven' was reviewed and approved, enabling members to continue using this term as well.

"This really opens up the opportunity to make an important key claim in user friendly consumer language."

Michelle Riddalls, Director, Regulatory Affairs - Country Cluster Lead Northern Europe, Pfizer Consumer Healthcare

#### A new partnership

PAGB decided to seek a new Primary Authority when changes to legislation were introduced which allowed organisations to enter into multiple partnerships. Uncertainty in the future regulatory landscape was also a factor in moving away from our previous partnership to one which we felt would be more effective and provide greater certainty for our Members.

We selected Cambridge and Peterborough from 418 possible local authorities because of its proven expertise in the interpretation and practical application of the Nutrition and Health Claims Regulation (NHCR) and the Food Supplements Regulations.

It has demonstrated a pragmatic approach to food standards and labelling, food supplements, and the use of the NHCR in advertising and marketing. We are confident that Members will benefit from this new partnership.

"PAGB has worked very hard to find and establish good relationships with one of the most competent Primary Authorities on food supplements. This working partnership has provided a number of pieces of helpful assured advice which give Members confidence in their marketing and labelling strategies."

Audrey Lamarche, Regulatory Project Manager, Bayer plc



#### What is Primary Authority Advice?

Primary Authority partnerships are formalised relationships between a local authority and either a business (direct partnership) or a trade association (coordinated partnership).

PAGB's coordinated partnership relates to the area of food standards and labelling and is therefore an important membership benefit for companies with food supplement products.

The Primary Authority provides robust and reliable PAA on the basis that, where it is followed, the regulators (for example Trading Standards) will treat the business as compliant.

PAA must be considered by local authority enforcement officers in inspections or when dealing with non-compliance. This provides industry with confidence that investment in compliance is not wasted and helps to safeguard against inconsistency.



of PAGB Members have food supplements products.

PAGB Members with food supplements products can join the Food Supplements Forum, a working group to keep members up to date on regulatory issues and enable member input on PAGB's work programme on food supplements.

See page 32 for more on PAGB Member working groups.

Responding to the challenges resulting from the UK's decision to leave the European Union has been a key priority for PAGB over the past year.



John Smith explains how PAGB stepped up to the challenge of EU Exit, despite continuing political uncertainty.

The potential impact of the UK leaving the EU has dominated discussions in our Regulatory Affairs Group and became the main focus of our public affairs programme. In the year since 1 July 2017 we have strengthened our position, developed resources and established PAGB as the voice of the consumer healthcare industry on EU Exit matters.

To effectively represent the industry, across the three categories of OTC medicines, self care medical devices and food supplements, we needed to fully understand the potential impact of EU Exit on our Members.

In November 2017, we established a new working group with PAGB Members to monitor developments and set priorities for PAGB engagement on a quarterly basis to ensure we could be nimble and react quickly to changes in the external environment. Our strategy for engaging with external stakeholders about EU Exit is twofold: to be the experts and to be vocal.

#### We aim to ensure our concerns are heard at the highest levels of Government and Parliament.

Alongside our ongoing engagement with MHRA, we continued an extensive stakeholder engagement programme which resulted in meetings with senior officials from the Department for Exiting the EU, the Department for International Trade, the Department for Business, Energy and Industrial Strategy and the Department for Health and Social Care. Our message to Government is clear:

When the UK leaves the European Union there should be no fewer over-the-counter products available in the UK and those products should be no less safe.

#### Our priority asks are (at June 2018)



Ensure appropriate mutual recognition agreements are in place to allow over-the-counter/self care products manufactured in the UK 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 regulations

44%

of UK exports went to the EU in 2015

### 20%

of the EU's pharmacovigilance is done by the UK

£1.5bn

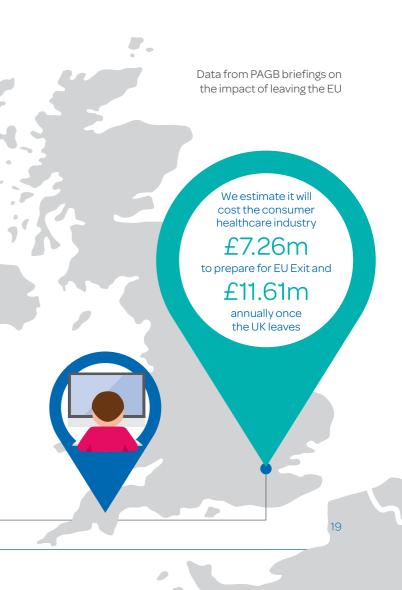
Imports of consumer healthcare goods in 2015 Members provided data to inform detailed briefings on the impact of uncertainty on current and future business planning which we shared with officials and Ministers in meetings, and more widely with stakeholders.



#### Working together we've delivered a strong message to the heart of Government.

PAGB's activity on EU Exit over the past year has resulted in a higher profile for PAGB and a greater understanding of consumer healthcare issues among politicians and policy makers.

As the negotiations over the UK's future relationship with the EU progress, we will build on this strong base to continue to create opportunities to be the experts and to ensure our messages are heard.



# Our strategy: **Be the expert. Be vocal.**



"PAGB has shown itself to be an effective voice for industry in expressing concerns about the future arrangements with the European Union".

Chris Mummery, Head of Northern & Southern Europe, Consumer Healthcare, Sanofi PAGB Vice-President

PAGB took its concerns about the implications of EU Exit to parliamentarians and policymakers.

John Smith gave oral evidence to the BEIS Select Committee inquiry 'Brexit and the implications for UK business: Pharmaceuticals', alongside the ABPI and BGMA (December 2017).



In the House of Lords, health spokesperson Baroness Jolly raised our issues in key debates.

#### Following briefings from PAGB, Baroness Jolly:

- tabled an amendment calling for regulatory alignment with the EU after withdrawal
- highlighted our concerns in two debates
- authored an article in Pharmacy Magazine
- secured a meeting with PAGB and Health Minister, Lord O'Shaughnessy

We issued joint letters and statements with associations representing the UK and EU pharmaceutical, life science and healthcare industries calling for ongoing cooperation between the UK and EU on medicines and on food supplements.

We contributed blog posts on EU Exit including for 'The UK in a Changing Europe', an initiative from the Economic and Social Research Council. **Our message was clear:** 

"The UK's continued close relationship with the EU is crucial to securing the continued supply of consumer healthcare products in the UK and the EU27 countries."

We produced briefings on the potential impact of EU Exit on access to over-the-counter products, and shared these with key stakeholders.



PAGB submitted responses to consultations and inquiries, setting out the concerns of the industry, with input from Members on the EU Exit Group.

#### April 2018

Post-Brexit UK-EU relations inquiry, House of Lords EU Select Committee

#### February 2018

Review on impact of EU Exit on medicines supply chains, Department of Health and Social Care

#### November 2017

Customs Bill: legislating for the UK's future customs, VAT and excise regimes, Government White Paper

#### November 2017

Brexit and the implications for UK business (pharmaceuticals) and Brexit and the implications for UK business (processed food and drink), Business Energy and Industrial Strategy Committee

#### October 2017

Brexit – medicines, medical devices and substances of human origin, Health and Social Care Select Committee We kept Members up to date on EU Exit developments through special events, in our regular Member communications and via our working groups.



In November 2017 we organised a seminar for PAGB Members and Associate Members with MHRA and BAH, the German Medicines Manufacturers' Association.



PAGB attended monthly roundtable meetings, organised by the Food and Drink Federation, to gather intelligence on potential consequences of EU Exit for food supplements.



Member companies met with consultants from EY to provide industry input to a government review of the impact of Brexit on the supply of medicines.



We began a quarterly survey of PAGB Members to inform our briefings with stakeholders.



We launched a dedicated EU Exit hub in the Members' area of the website and established a weekly e-newsletter to keep Members up to date on developments.



One of our key strategic priorities is to be the voice of the industry and respond to the media on issues relating to over-thecounter products and self care.

In the year to 30 June 2018, the most frequently occurring media issues on OTC medicines related to the price of branded medicines compared to generics and new research into the safety and efficacy of analgesics.

The number of media issues on food supplements remained low. The efficacy of vitamins, minerals and supplements; children's vitamins; and fish oils were most frequently covered.

We aim to secure the inclusion of a quote from PAGB in media coverage to provide balance to stories which could otherwise undermine the public's confidence in the safety or effectiveness of over-the-counter medicines and medical devices.

We worked with the London Fire Brigade to help raise awareness of the appropriate use of OTC products in the light of tragic events relating to flammability of fabrics that had absorbed paraffin-based emollients.

#### Year to 30 June 2018 Number of media issues

61 18 medicines food supplements and devices Pieces of reactive coverage

6 and devices

food supplements

#### % coverage balanced

94%

74

medicines

including **PAGB** quote 80% including

HSIS quote

"PAGB has been a strong voice for the industry again this year. It has produced clear position statements and supporting quotes that have provided balance to media coverage on new and recurring issues. We continue to be impressed with the efficiency and quality of PAGB's media work, which reinforces that PAGB, and its members, have a credible voice in the media."

Iona Gilbert, Communications Director Consumer Healthcare, GSK

HSIS produced reports and proactive comment on nutrition issues.

In July 2017, an HSIS report on the importance of nutrition in the middle years (40-70 years) included details of the nutrients necessary to support healthy ageing.



**Dietician and HSIS** expert Dr Carrie Ruxton presented the results at Food Matters Live, November 2017.

In May 2018 HSIS addressed the growing trend in veganism and vegetarianism, with a practical guide to how to ensure you're not missing out on valuable vitamins and minerals.



PAGB funds the Health and Food Supplements Information Service (HSIS), which works with

We continued to press for a National Strategy for Self Care, supported by practical policy solutions to support implementation.

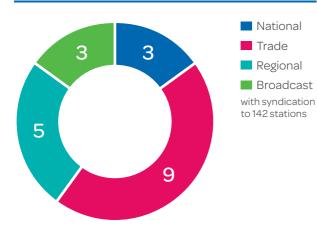
#### **Recommendation prescriptions**

PAGB policy priority:

Introduce "recommendation prescriptions" for GPs to recommend over-the-counter products to patients.

In April 2018, PAGB launched a campaign calling for the introduction of recommendation prescriptions for GPs to suggest appropriate overthe-counter (OTC) treatments and give self care advice to people with self-treatable conditions.

#### Coverage in print and online media





Our media campaign was supported by online and social media activity. We also produced a video, in which GP Dr Sarah Jarvis explained how recommendation prescriptions would help GPs manage CCG prescribing guidance (see page 26 for more on this guidance).

The NHS is overstretched and experiencing increasing demand, especially in primary care, often leading to long waits for GP appointments. The benefits of promoting self care for selftreatable conditions are increasingly being recognised as one of the ways to reduce demand and to work towards a more sustainable NHS.

PAGB is confident that 'recommendation prescriptions' would make a positive difference to self care in the UK, saving the NHS money and reducing demand on stretched services.



#### Malnutrition

PAGB worked with the Shadow Health team to raise the profile of malnutrition as a political issue and position food supplements as part of the solution.

+20% pregnant women admitted to hospital with primary or secondary diagnosis of vitamin D deficiency over the past year

+22%

people admitted to hospital with malnutrition as primary or secondary diagnosis since 2010

Answers to parliamentary questions revealed the scale of the problem and were used by the Opposition to secure media coverage calling for action. Shadow Secretary of State for Health, Jonathan Ashworth MP, also highlighted concerns around malnutrition in his party conference speech.

#### Self care and NHS sustainability

PAGB policy priority:



#### Publish and implement a National Strategy for Self Care.

Using an infographic developed with the Self Care Forum and the RCGP, we briefed MPs and key stakeholders on the need for a National Strategy for Self Care.

'Saving time, reducing demand' explained how empowering people to self care could save time and reduce demand on the NHS.

A national strategy must be supported by tangible policies to maximise the opportunity of self care. PAGB highlighted these practical steps through its policy and public affairs campaigns.

PAGB's campaign was shortlisted for a Communique Award: Excellence in Communications – Payers/PolicyMakers (June 2018)

#### NRT programme

PAGB policy priority:

#### Pledge to continue support for NHS smoking cessation services to further reduce smoking rates in the UK.

We produced a series of case studies outlining the expected return on investment for areas with different demographics.

In June 2018, we organised an expert roundtable meeting, chaired by Bob Blackman MP, to agree a set of recommendations to deliver improvements in evidence-based smoking cessation services.

On 29 March 2018 the NHS issued guidance to CCGs on conditions for which over-the-counter items should not routinely be prescribed.



Donna Castle explains how PAGB responded to the introduction of this guidance and what it means for the future of self care.

The NHS in England has taken a significant step towards encouraging people to self care for self-treatable conditions, by issuing guidance to Clinical Commissioning Groups (CCGs) that prescriptions for OTC products should no longer routinely be offered for self-limiting conditions and minor conditions suitable for self care.

The guidance aims to reduce unnecessary variation in prescribing patterns across England and reduce demand on overstretched GP services.

NHS England estimates this will save the NHS



The relevance of this guidance to PAGB's Members is clear and we responded in detail to both rounds of consultation. We ran a comprehensive policy development process to understand PAGB Member views on the impact of restricting prescribing for OTC medicines and develop a consumer healthcare industry position. Despite there being a range of views within the PAGB membership, all agree that encouraging and supporting people to self care is an important and positive step.

PAGB represented the industry at webinars and stakeholder meetings, and we secured a separate meeting for PAGB Members with officials from NHS England and NHS Clinical Commissioners. Our consultation responses highlighted the need to take a system-wide approach and ensure supporting policies are put in place to enable people to self care, rather than just implementing restrictions on prescribing.

> We secured a number of important changes to the original proposals, most significantly the exclusion of treatments for long-term conditions from the guidance.

We argued strongly against the proposal to use the safety and efficacy of medicines as criteria to determine which products would be restricted and were pleased that the guidance takes a conditionbased, rather than product-based approach so judgements on safety and efficacy are not used.

We also opposed the use of the term 'low clinical value' in the first consultation and were pleased this language was removed from the final guidance.

### Changes to the guidance after consultation:

- ✓ Focus on increasing self care
- Language changed from 'low value' to 'limited evidence'
- ✓ Safety and efficacy no longer assessment criteria
- ✓ Long-term conditions taken out of scope

While PAGB maintains that a National Strategy for Self Care is needed to provide the leadership and policy coordination necessary to facilitate population-wide behaviour change, this change to prescribing practices is a positive step forward.

> This guidance should be seen as an opportunity to support more people to self care for self-treatable conditions.

"PAGB's policy development process to agree an industry position was excellent. I was impressed by the quality of the consultation responses and the opportunities the PAGB team created to influence the process."

Barry Draude, Managing Director, Thornton & Ross



Our self care campaigns

Understanding the importance of self care is crucial for the future sustainability of the NHS.



#### Making the case for self care



Following on from the launch of the PAGB Self Care Nation report in 2016, we published new statistics and an infographic to mark Self Care Week in November 2017.

The results showed that concerns around waiting times for GP appointments are causing some people to exaggerate their symptoms to see a doctor sooner, when in many cases their pharmacist could offer the support and treatment they need.



PAGB used the survey findings to support our policy calls on the importance of improving health literacy and promoting the expertise of pharmacists.

Eight leading consumer journalists attended a PAGB briefing dinner with pharmacist Hemant Patel and A&E nurse Victoria Hupe.

Our guest speakers shared their experiences of people's attitudes and behaviours towards self care.

PAGB's policy priorities:

Launch a national campaign to promote the expertise of pharmacists

Continue and expand national self care campaigns, such as Stay Well This Winter



2017-18 was the 3rd year in which PAGB and its Members supported the NHS Stay Well This Winter campaign.

supporting
STAY WELL

We were please to partner with Public Health England for its new, year-round Stay Well campaign which launched in February 2018.

#### Self Care Week

Self Care Week is organised by the Self Care Forum and aims to provide a focus for self care activity across the country. The Self Care Forum provides resources and ideas to health professionals to help promote the importance of self care.

In November 2017, Self Care Week messages reached over 22 million people. An even wider range of organisations than ever before took part.



PAGB participated in Self Care Week in 2017 and we encouraged our Member companies to do the same.



#### Supporting GPs to embrace self care

In September 2017, PAGB launched an online version of its popular OTC Directory to support healthcare professionals giving advice on self care.



We saw an increase in demand for the PAGB OTC Directory in addition to the 59,000 copies distributed to GPs and other health professionals in 2017.

Requests came from a broader range of healthcare professionals seeking information to support people to self care.



#### PAGB's policy priority:

Include self care and methods of supporting people to self care, in the professional training curriculum for GPs and other healthcare professionals.

We responded to the General Medical Council's (GMC) consultation, welcoming proposals to include specific self care outcomes in the GMC standards for newly qualified doctors. (January 2018)

### A report from the joint chairs of the Self Care Forum

Dr Pete Smith OBE and Dr Selwyn Hodge

#### It has been a crucial year for the Self Care Forum and for self care in general.

The impact of the Self Care Forum's work can be seen in the way that self care has become a common expression, even making it into the dictionary in 2017, and in the recognition across Government that self care should be considered a serious part of the solution to challenges within the NHS.

The Self Care Forum's online course on how to conduct a self care aware consultation and our 14 fact sheets were recommended to support GPs following national guidance on OTC prescribing. In May 2018 we were invited by NHS England to submit a proposal for funding to develop additional factsheets to include in a toolkit for GPs. This proposed toolkit will be an important resource to help provide consistency of message as the guidance is implemented.

In the year to 30 June 2018 the Self Care Forum met with MPs to seek support for self care policies, and began work on a roundtable event in Parliament to examine ways to progress a national self care strategy, in partnership with PAGB and the RCGP.



The Self Care Forum is an independent charity whose aim is to further the reach of self care and embed it into everyday life. PAGB provides funding to support the day to day running of the organisation.

#### Supporting a self care aware workforce

The influence of the Self Care Forum stretches beyond its relationship with NHS England, Public Health England and policy makers in Parliament.

Its strength is also in its relationships with regional and local NHS teams, local authorities, nurses, GPs, pharmacists... with the people who are helping support self care in the community.

Self Care Week is one of the ways we achieve this.

In 2017 Self Care Week reached over 22 million people in England, that's a third of the population. The diversity of participating organisations is a recent phenomenon and one which we strongly encourage.

#### + #selfcareweek trended on 13 November

We saw a 50% increase in the number of organisations participating in Self Care Week in 2017.

#### Number of organisations

2016: **200** 2017: **300** 

We provided resources on our website and via social media to raise the profile of Self Care Week.

selfcareforum.org (Sept-Nov 2017)

45,000

7,300

page views

factsheet views

@selfcareforum

381

85.5k

new followers

impressions +18%



#### Looking to the future

The Self Care Forum launched an exciting new partnership with Imperial College and the International Self Care Foundation in November 2017. The Self Care Academic Research Unit (SCARU) is the UK's first academic group dedicated specifically to research into self care. It aims to make the absolute case for self care.

Our aim is to secure a commitment from national and European leaders to work together to embed self care at a national level.



#### Our Annual Self Care Conference will be replaced by a Self Care Summit in November 2018.

Our next challenge is to go beyond the 'why' of self care and demonstrate how it can be embedded in everyday life. As we prepare our future strategy, the Self Care Forum would like to thank PAGB for its support since 2011 and looks forward to a continued collaboration to meet our mutual aims.

"PAGB congratulates the Self Care Forum on its achievements. In December 2017 we provided additional resources to enable the charity to develop a business plan and sustainable strategy for its future. We look forward to a healthy partnership with the Self Care Forum for many years to come." Representatives from Member companies contribute to PAGB's work programme on regulatory, advertising, public affairs and communications matters via working groups.

#### PAGB Board (at 30 June 2018)

### Representatives from the following companies:

Alliance Pharmaceuticals Ltd Bayer Plc Ceuta Healthcare DDD Limited GR Lane Health Products Limited GSK Consumer Healthcare infirst Healthcare Ltd Johnson & Johnson Limited The Mentholatum Company Limited Merck Consumer Health Perrigo Pfizer Consumer Healthcare Ltd RB UK Commercial Ltd Sanofi Thornton & Ross Ltd

#### Member working groups

There are currently seven groups, four of which are sub committees of the Board (indicated by \*). We create sub groups and ad-hoc working groups on specific issues as they arise.

#### **Regulatory Affairs Group\***

Regulatory issues for OTC medicines and self care medical devices.

Sub-groups: Naming, Reclassification (Switch), Medical Devices, Pharmacovigilance, and ingredientspecific groups on an ad-hoc basis.

#### regulatory@pagb.co.uk

#### EU Exit Group\*

PAGB policy priorities for EU Exit; public affairs engagement; regulatory issues. New in February 2018.

#### john.smith@pagb.co.uk

#### Medical Devices Regulatory Group

Regulatory policy and projects on self care medical devices; Medical Devices Regulation.

Sub-group of the Regulatory Affairs Group.

regulatory@pagb.co.uk

#### Food Supplements Forum

Food supplements regulatory updates; ingredients; Health and Food Supplements Information Service (HSIS) updates.

tccallis@pagb.co.uk

#### Public Affairs and Communications Group\*

Media issues; policy development and public affairs campaigns

donna.castle@pagb.co.uk

#### Advertising Working Group\*

PAGB advertising codes and guidance.

laura.kelly@pagb.co.uk

#### Associate Member Working Group

Ideas and review of PAGB services relevant to Associate Members. New in May 2018.

katharine.mason@pagb.co.uk

#### Want to know more?



Email the named PAGB contact or go online for Terms of Reference and full group membership. (Member log-in required)

#### Spotlight on the Regulatory Affairs Group

"I have chaired the Regulatory Affairs Group (RAG) for a number of years now but never before has the future been more uncertain. Brexit has impacted us all, and PAGB has had a significant role in play, by combining forces with other trade associations but also representing the specific needs of our Industry, in working with MHRA and Government officials to help shape the future of the UK Regulatory framework.

It is important that our workplan is not completely dominated by EU Exit activities and we have continued to have ongoing dialogue with the MHRA to make continuous improvements on the reclassification process. Sustainability is also becoming more important with PAGB contributing to some key consultations such as single use plastics.

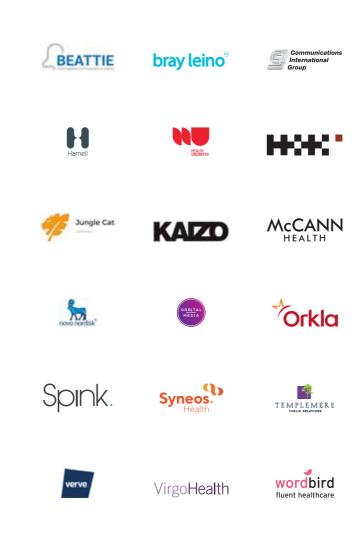
These are interesting times and we look forward to sharing progress with you over the coming months."

Gill Peckham, Director of Regulatory Affairs Northern Cluster, Johnson & Johnson Ltd



**Our Associate Members** 

ALLIANCE	Solutions with you in mind		BAUSCH+LOMB	BAYER R
Bristol Laboratories	Combridge Transcer Legebal Linked	Catalent.		
Clasado	COLGATE-PALMOLIVE COMPANY	COMBE	<b>Cuxson</b> Gerrard	
DERMAL TOPICAL INNOVATION	ernestjackson	( the second	SALDERMA	(Lanes In All
<b>G</b> Glenmark	gsk	<b>Aisamitsu</b> .	HRAPharma	
Johnson+Johnson	MANX Healthcare	Mentholatum Reference	Merck	Mölnlycke <sup>®</sup>
<b>Mylan</b>	Perrigo	Pfizer Consumer Healthcare	PrestigeBrands	PRG
HEALTH - HYGIENE - HOME	SANOFI	SFI	TEVA	Tierritas & Ross
ucb		Wockhardt		



### AESGP 🤽

PAGB is a Member of AESGP, the Association of the European Self Medication Industry.

The UK's position in Europe may be changing but PAGB remains committed to partnership with our colleagues in consumer healthcare associations across Europe. We've influenced European initiatives impacting on our Members including digital healthcare, medical devices regulation and pharmaceuticals in the environment.























Through AESGP, we are also represented on WSMI (World Self Medication Industry Association) which aims to promote self care at a global level.

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#### A short guide to who does what at PAGB.

Left to right:

#### John Smith, Chief Executive

Strategic overview; representing the industry on national and international bodies; spokesperson on consumer healthcare issues: EU Exit.

#### Donna Castle, Director of Public Affairs and Communications

Media relations including HSIS; PAGB policy positions; EU Exit, public affairs and stakeholder relations.

#### Katharine Mason, Director of Regulatory and Legal Affairs

Regulatory affairs; EU Exit; ingredients issues; oversight of advertising and regulatory services; governance.

#### Advertising services

Copy advice and approvals; workshops; compliance; codes and guidance.

Laura Kelly, Advertising Manager Jenny Capel, Codes of Practice Assessor Victoria Trowse, Codes of Practice Assessor

#### **Regulatory Services**

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

Aneeta Cameron, Regulatory Consultant to PAGB TC Callis, Food Supplements Regulatory Manager Bethany Collison, Regulatory Executive

#### **Public Affairs and Communications**

Promoting PAGB campaigns and the consumer healthcare industry to stakeholders; Member communications; PAGB website; self care campaigns.

Nikki Kennedy, Communications Manager Libby Whittaker, Public Affairs Executive and Self Care Forum coordinator

#### **Operations and Administration**

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

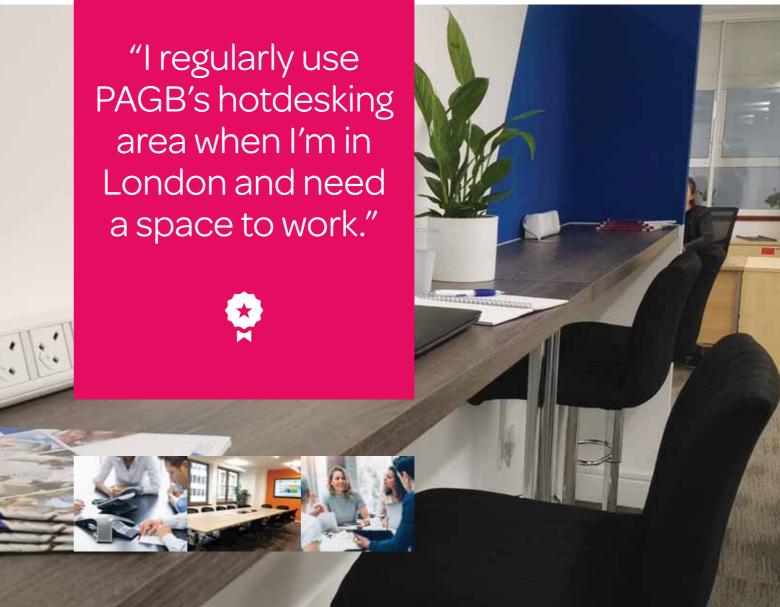
#### Lauren Higgins, Reception and Operations Assistant

Lorraine Lee, Membership Secretary; **Finance and Facilities Manager** 

Sandra Smith, Operations Assistant Finance

Pauline Young, HR and Administration Manager; PA to management team

"I regularly use area when I'm in London and need a space to work."



#### "...It's great as it means I can still work effectively when I'm out of the office."

#### Sophie Fairweather, Senior Medical Information Associate, Alliance Pharma plc

In a modern, refurbished space we've been able to bring our IT and infrastructure up to date, and we've created well-equipped meeting spaces that Members can hire for a few hours or a full day.

#### www.pagb.co.uk/about-us/room-hire

Meeting rooms and hotdesking subject to availability, pre-booking required.

Up to 20 boardroom style / 35 theatre style in our large meeting room. Up to 8 in the small meeting room.

Free to Members for the use of Member company UK teams only.

Reduced rates for Associate Members.









