Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs

Response from PAGB
5 October 2017

PAGB (Proprietary Association of Great Britain) welcomes the opportunity to respond to NHS Clinical Commissioners and NHS England about proposals to introduce guidance on prescribing certain products in primary care.

This response is from PAGB in the capacity of a trade association representing the consumer healthcare industry. The consumer healthcare industry in the UK offers people a range of solutions to self care for self-treatable conditions, such as pain relief, coughs, colds, and sore throats, gastrointestinal problems, skin treatments, hayfever and allergies, and eye and foot care.

We have read the document *Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*.

Summary

- It is **vital to promote and empower more people to self care**, rather than use GP and A&E services for conditions which could be self-treated at home or with advice from a pharmacist.
- Taking a system-wide approach to self care has the potential to release greater efficiency savings (> £2bn) than those outlined in the consultation document.
- **A national strategy for self care is required** to provide the leadership and policy co-ordination necessary to embed self care into the NHS and people's lives.
- Measures which should be introduced under a national self care strategy should include:
    - policies to make it easier for people to buy over-the-counter (OTC) products e.g. **reducing the VAT rate** and **increasing the number of medicine reclassifications**;
    - offering **GPs 'recommendation pads'** so they can recommend rather than prescribe OTC medicines;
    - tools to **empower pharmacists** to support self care;
    - action to **improve health literacy** and steps to **support people to live healthier lives**.
- Introducing prescribing restrictions before implementing measures to support greater self care could result in unintended consequences which place a higher burden on NHS services.
- **Safety and efficacy should not be assessment criteria** for prescribing restrictions. OTC medicines on the market in the UK have demonstrated clear evidence of a good safety profile, efficacy to treat the condition it is indicated for and suitability for self care. Any concerns about the safety of medicines should be addressed through existing MHRA regulatory processes.
- It is **important that healthcare professionals continue to have the ability to use their clinical judgement in making prescribing decisions**, particularly with regards over-the-counter medicines that are prescribed for the treatment of long-term or serious conditions, or to prevent illness and disability (and therefore NHS costs) in the future.
- Greater clarity is needed about next stages of consultation. **PAGB can bring insights and value to future discussions on this guidance**. We would therefore welcome the opportunity to participate on the joint clinical working group which is developing the proposals.

PAGB, Vernon House, Sicilian Avenue, London, WC1A 2QS 020 7242 8331 info@pagb.co.uk www.pagb.co.uk

1. Overarching comments

1.1 PAGB recognises the challenging financial situation currently facing the NHS and supports the aim to ensure NHS resources are used in the most efficient way possible. We fully support the drive to empower more people to take responsibility for their own health and wellbeing and self care for self treatable conditions. This is something we have been working towards for a number of years and we feel there are several supporting policies which would need to be put in place before any prescribing restrictions are considered in order to achieve the stated objectives of making local prescribing practices more effective and releasing savings to reinvest into improving patient care.

1.2 PAGB has been calling for a national strategy for self care to provide the leadership and policy co-ordination necessary to support widescale behaviour change. This is a complex issue which cannot be addressed without a system-wide approach. Measures which should be implemented to support greater self care, as part of a national strategy, include:

- **Increase access to effective over-the-counter medicines/products**
  - Zero-rate VAT on over-the-counter products
  - Introduce a target to increase the number of POM-P/GSL reclassifications
  - Introduce "recommendation prescription" pads for GPs to recommend over-the-counter products to patients
- **Empower community pharmacy to facilitate self care**
  - Launch a national campaign to promote the expertise of pharmacists
  - Enable community pharmacists to have "write" access to people's care records
  - Enable community pharmacists to refer people to other healthcare professionals, fast-tracked if necessary
  - Improve NHS 111 algorithms to appropriately refer more people to community pharmacy
- **Improve health literacy**
  - Continue and expand national self care campaigns, such as Stay Well This Winter
  - Include health education in the PSHE school curriculum for ages 5-18
  - Include self care, and methods of supporting people to self care, in the professional training curriculum for GPs and other healthcare professionals
- **Support people to live healthy lifestyles and prevent ill health**
  - Recommend all adults take a daily multivitamin and fish oil supplement
  - Pledge to continue support for NHS smoking cessation services.

1.3 PAGB research has found that there are 57 million GP appointments and 3.7 million visits to A&E every year for self-treatable conditions which people could have asked a pharmacist for advice about and could have successfully treated with an over-the-counter medicine. We estimate this costs the NHS as much as £2.3 billion a year[1,2]. This magnitude of savings cannot be released through changes to prescribing practices alone, but taking a system-wide approach to self care, as outlined in 5.2, could offer considerably greater opportunities to deliver significant savings.

[1] IMS Health, Minor ailment workload in general practice, 2007 https://www.pagb.co.uk/content/uploads/2016/06/Driving-the-self-care-agenda-AndyTisman.pdf
[2] IMS Health study of self-treatable conditions presenting in A&E units 2014. https://www.pagb.co.uk/content/uploads/2016/06/PAGB_AE_Executive_Summary_June-2015.pdf

1.4 Furthermore, we know that many medicines are taken incorrectly or not at all, so we would urge greater efforts to address medicines compliance and medicines optimisation, in line with NICE recommendations that people, particularly those with long term conditions, should be offered a structured medicines review[3].

1.5 PAGB understands that several Clinical Commissioning Groups (CCGs) are already implementing local restrictions on prescribing[4] and we support attempts to provide consistency in guidance for healthcare professionals and to prevent the emergence of a postcode lottery in prescribing practice. An evaluation of the impact of restrictions in these CCG areas should be carried out and other self care measures considered before national guidance is issued.

1.6 We support the assertion on p4 of the consultation document that the proposed guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. PAGB believes it is vital that healthcare professionals should be able to continue to use their clinical judgement on appropriate prescribing, particularly with regards over-the-counter medicines that are prescribed for the treatment of long-term or serious conditions, or to prevent illness and disability (and NHS costs) in the future.

1.7 People should be at the heart of policy making, particularly in relation to self care. Restricting healthcare professionals' ability to prescribe without offering additional support to empower people to self care could result in an increase in GP appointments or additional demand on other parts of the system from people confused about how to manage their own health conditions or who fail to treat their condition because they have not been given a prescription. Healthcare professionals could also face pressure to prescribe something else instead, which could negate any potential savings.

1.8 PAGB is concerned about the use of the term 'low clinical value' in this consultation. This undermines the principle of self care. People are less likely to buy or trust a medicine if they think the NHS is telling them it has a low clinical value, which may result in them returning to the GP for a stronger medicine that they may not need. If an individual finds that a particular treatment effectively relieves their symptoms, it does not have low clinical value to them, and if it means they don't need to visit a GP or A&E, it does not have low value to the NHS. We would prefer to see greater recognition and a more positive representation of the important role self care and over-the-counter products play in supporting the NHS and people's health and wellbeing.

2. Equality and Health Inequality

2.1 Do you feel there are any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?

2.1.1 Pregnant women and children are entitled to free prescriptions, therefore would be disproportionately affected by any prescribing restrictions. If pregnant women and children

[3] NICE, Medicines Optimisation, Quality Standard QS120, published 2016. https://www.nice.org.uk/guidance/qs120/chapter/quality-statement-6-structured-medication-review

[4] CCGs which have already introduced prescribing restrictions include: North Kirklees CCG, Greater Huddersfield CCG, East Cheshire CCG, South Cheshire CCG, Vale Royal CCG, Lincolnshire East CCG, Lincolnshire West CCG, South West Lincolnshire CCG, South Lincolnshire CCG, Sheffield CCG, Stockport CCG, Enfield CCG, Bristol CCG, Brighton and Hove CCG, East Kent Prescribing Group (covers: Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG).

do not get access to the medicines they need this may result in further problems or increased costs in the future. For example:

- There are data to show that with proper emollient therapy, which can only be assured through appropriate prescribing and monitoring, the atopic march can be prevented in infants and children. This means it is possible to reduce the incidence of asthma and other atopic diseases occurring in the future. In this example, the primary and secondary care costs of a child developing asthma will far outweigh the cost of emollient prescriptions.
- People with acne may spend too long using over-the-counter products before seeking medical advice, in which time the acne worsens. Therefore, when they do consult the GP they require more expensive prescription medicines which also need expensive monitoring. In addition, there are longer term costs associated with not getting the right acne treatment early enough, including scarring which can affect mental health and result in workplace issues.

2.2 Do you feel there is evidence we should consider in our proposals on the potential impact on health inequalities experienced by certain groups e.g. people on low incomes, people from BME communities?

2.2.1 PAGB is concerned about the potential impact of these proposals on health inequalities. In particular, groups on lower incomes, with long-term conditions or multimorbidities, or with lower levels of health literacy could be disproportionately impacted by these proposals. PAGB has been calling for action to improve health literacy (as outlined in 1.2) as levels of health literacy in the UK are low[5].

2.2.2 Although the average cost of an over-the-counter medicine is £2.94[6], there is a wide variation in prices with some costing more than £25.00. While it may be possible for an individual on a low income to purchase one of the less expensive medicines, if they require a more expensive treatment it may not be affordable. Equally someone on a lower income may be able to cover the one-off cost of a medicine for a short-term condition, but may not have the resources to repeatedly buy a medicine every week or month to treat a long-term condition.

2.2.3 In 2015, 89.7% of prescription items were dispensed free of charge and a further 4.7% were dispensed to people who had purchased pre-payment certificates. PAGB research in 2016 found that 29% of people who qualified for free prescriptions would be willing to purchase an OTC medicine for a self-treatable condition, instead of visiting the GP for a prescription, if they knew if it would save the NHS money[7]. Therefore, educating people about self care and the benefit it can have to both themselves and the NHS could go a long way to reducing prescribing for OTC medicines, without the need to introduce restrictions.

2.2.4 We call on the Government to urgently carry out a full impact assessment on these proposals and publish the results for further consultation.

[5] In 2014, the Royal College of General Practitioners Health Literacy Report found that that health information is currently too complex for more than 60% of working age adults in England to understand
[6] PAGB analysis of Nielsen data, 25 March 2017.
[7] PAGB, Self Care Nation report. Survey of 5,011 UK adults. Published November 2016 https://www.pagb.co.uk/latest-news/report-self-care-nation-self-care-attitudes-behaviours-uk/

3. Section 3: How will the guidance be updated and reviewed?

3.1 Joint clinical working group annual review of guidance

3.1.1 PAGB would like to see greater clarity about the process by which the joint clinical working group will review the guidance annually (p9 of the consultation document).

3.1.2 As the representative body for the consumer healthcare industry which manufactures and markets the over-the-counter products to which this consultation refers, PAGB can bring insights and value to future discussions on this guidance. We would therefore welcome the opportunity to participate on the joint clinical working group which is developing the proposals.

3.1.3 Manufacturers of any products being considered for review in the future should be directly notified in advance and have the opportunity to engage in discussions at an early stage.

3.2 Concern about PrescQipp

3.2.1 PAGB members have concerns about the PrescQipp process by which the first 18 medicines were identified for review. To support any future assessment using the PrescQipp model we would need to know which data and evidence was used to make recommendations.

4. Section 4: Proposals for CCG Commissioning Guidance

4.1 PAGB represents its member companies with regard to the products in the over-the-counter medicines, substance-based self care medical devices and food supplements categories. Therefore, the products identified in section 4 to which our comments refer are: glucosamine and chondroitin, herbal treatments, lutein and antioxidants, omega-3 fatty acid compounds and rubefacients (excluding topical NSAIDs).

4.2 Do you agree with the proposed recommendation for herbal treatments

4.2.1 We disagree with the proposed recommendation.

4.2.2 Herbal treatments on the market in the UK have a medicines licence based on traditional use. We feel it is unhelpful for NHS Clinical Commissioners and NHS England to suggest that these products have low clinical effectiveness as this undermines the basis upon which these products have received a licence.

4.2.3 There are a wide range of medicines available in the UK with a Traditional Herbal Registration. This provides people with choice. We do not believe it is appropriate to group all herbal medicines together for consideration in this way.

4.3 Do you agree with the proposed recommendation for glucosamine and chondroitin, lutein and antioxidants, omega-3 fatty acid compounds.

4.3.1 We disagree with the proposed recommendation for glucosamine and chondroitin, lutein and antioxidants, omega-3 fatty acid compounds.

4.3.2 These products are food supplements. Foods cannot make any claim to treat, prevent or cure any disease state. However, they are permitted to claim beneficial effects where there is evidence to do so. Such evidence must show a benefit in healthy populations only; it cannot show evidence of efficacy in a diseased population and it cannot make use of data

from animal studies. It is a key regulatory requirement that all food must be safe and be of the quality and nature expected by consumers.

4.3.3 Food supplements are intended to supplement the diet; they cannot claim or imply that they can replace a varied and balanced diet, however, they have an important role where people are unable or unwilling to eat a varied and balanced diet. For example, people who cannot meet the recommended two portions of fish a week, one of which is oily fish, may benefit from taking an omega-3 supplement.

4.3.4 The National Diet and Nutrition Survey (NDNS) shows that there are clear nutrient shortfalls in the UK diet. Only 27% of adults aged 19-64 meet the 5-A-Day recommendation for fruit and vegetable intakes[8]. One fifth of adults have low levels of vitamin D in the summer, a quarter in autumn and winter[5]. The NDNS also shows intakes well below the recommended level of multiple other nutrients including vitamin A, iron, riboflavin and vitamin B12[5] as well as oily fish (a key source of omega-3)[5]. Men and women in their middle years (40-65) have intakes below the lower reference nutrient intake (the level at which deficiency is likely to occur) for ten essential nutrients – vitamin A, riboflavin, folate, calcium, magnesium, potassium, iron, zinc, selenium and iodine[9].

4.3.5 Low micronutrient intake levels are associated with a generally higher incidence of morbidity and mortality from all causes, particularly as we age. The increasingly ageing population within the UK is already raising concerns about costs to the NHS. Providing greater knowledge of nutrition as well as access to and understanding of the use of food supplements could have substantial cost benefits.

4.3.6 More than 600,000 people in the UK are affected by AMD[10]. The Age Related Eye Disease Study (AREDS), conducted by the National Eye Institute in America, found that high dose vitamin C, vitamin E, beta carotene and zinc significantly reduced the risk of advanced age related macular degeneration (AMD) and its associated vision loss. The study has generated a substantial body of peer review publication[11] which largely concludes that the use of both zinc and antioxidants in supporting eye health is effective in reducing deterioration. Several years after AREDS concluded the Age Related Eye Disease Study 2 (AREDS2) was run as a multi-centre randomised trial designed to assess the effects of supplementation with lutein, zeaxanthin and DHA and EPA on the progression to advanced AMD; inclusion criteria for the study ensured that only individuals at high risk of developing advanced AMD were included. As with the first AREDS study, AREDS2 has generated a large body of peer review publication[12]. At least one such review concluded that the combination of lutein and zeaxanthin were more appropriate than beta-carotene in AREDS type supplements.

4.3.7 Evaluation of relevant scientific data by the European Food Safety Authority (EFSA) has resulted in the authorisation of health claims for both docosahexanoic acid (DHA) and

[8] National Diet and Nutrition Survey
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/551352/NDNS_Y5_6_UK_Main_Text.pdf
[9] Ruxton C and Derbyshire E (2017) Nutrition in the Middle Years. Complete Nutrition
[10] https://www.macularsociety.org/age-related-macular-degeneration-0?gclid=CL2ehbyL69UCFS237Qod-vYHJw
[11] https://www.ncbi.nlm.nih.gov/pmc/?term=AREDS
[12] https://www.ncbi.nlm.nih.gov/pmc/?term=AREDS2

eicosapentanoic acid (EPA) in maintaining normal blood triglyceride levels, maintaining normal blood pressure and in supporting the normal function of the heart[13] [14] [15] [16].

4.4 Do you agree with the proposed recommendation for rubefacients

4.4.1 We disagree with the proposed recommendation for rubefacients.

4.4.2 Rubefacient products available as over-the-counter medicines in the UK are effective for relieving pain in musculoskeletal conditions. It is our estimation that prescribing an alternative to these products would cost the NHS significantly more than the cost of continuing to offer these products.

4.4.3 A number of topical analgesics, which have been available on prescription for many years have been incorrectly classified as rubefacients. We request the publication of a list of the products being considered in this category and ask NHS England and NHS Clinical Commissioners to engage with the manufacturers of those products to ensure clarity on the appropriate classification of each one.

5. Section 5: Items that are prescribed in primary care and are available over-the-counter

5.1 Please provide your views and any relevant evidence that we should consider when developing proposals to potentially restrict items that are available over-the-counter.

5.1.1 PAGB believes it is necessary to take a system-wide approach to the need to increase people's self care behaviour. A national strategy for self care should be implemented with a package of measures (not simply introducing prescribing restrictions) to empower people with time-limited/short-term self-limiting conditions to self care, rather than visit the GP for a prescription. We have concerns about taking a blanket approach to restricting prescriptions of medicines that are available over-the-counter, but are being used for longer term or chronic conditions.

5.2 Promoting and supporting self care for self-treatable conditions

5.2.1 We recognise and support the NHS' desire to ensure spending is as efficient as possible and believe this puts a greater focus on the opportunities to further the self care agenda. Introducing prescribing restrictions in isolation cannot tackle the complex issue of people's behaviour with regard to their own health and wellbeing – and with it, the resulting impact on NHS services. As outlined previously a national self care strategy is needed to ensure the right package of measures is put in place to educate and empower people to feel confident in looking after their own health.

5.2.2 PAGB research in 2016 found that although 92% of people said it was important to look after their own health to ease the burden on the NHS, when they felt unwell, the GP would be the first port of call for 34% of people[17]. There seems to be a disconnect between people's understanding of how health services should be used, their stated good intentions and what they actually do when they feel unwell.

---

[13] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1734/epdf
[14] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2009.1263/epdf
[15] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1796/epdf
[16] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2078/epdf
[17] PAGB, Self Care Nation report. Survey of 5,011 UK adults. Published November 2016 https://www.pagb.co.uk/latest-news/report-self-care-nation-self-care-attitudes-behaviours-uk/

5.2.3 This consultation has put access to medicines in the spotlight. It is important to increase the access people have to effective over-the-counter medicines that they can use to self-treat. We have been encouraged by the recent POM-P reclassifications for anti-malarials, allergy and psoriasis and we look forward to further reclassifications which increase access and choice for people faced with a condition that is suitable for self care. We urge the NHS to work with the MHRA to support further reclassifications.

5.2.4 We have called for the introduction of "recommendation prescription" pads for GPs to recommend an over-the-counter medicine for a patient to buy if they attend the surgery with a self-treatable condition. We feel this would be a positive way to support the individual in accessing the right treatment. In Germany, a similar scheme has been very effective. The Grüne Rezept (Green Prescription) is a prescription pad on which GPs can recommend an OTC medicine to their patient. Research conducted by BAH, the German Medicines Manufacturers Association, in November 2016 found that when people were given a green prescription by their GP, 87% purchased the recommended medicine from a pharmacy and 4% purchased the recommended medicine from an online pharmacy. Only 6% said they did not purchase the medicine and 3% couldn't remember. BAH also found that people remembered the GP's recommendation and the next time they experienced the same symptoms they went directly to the pharmacy without visiting the GP first.

5.2.5 PAGB would urge the Government to consider reducing the VAT rate on over-the-counter medicines, self care medical devices and food supplements. Currently the majority of medicines attract the standard rate of 20%, however nicotine replacement therapy has a reduced rate of 5%. While there would be a tax-revenue implication of reducing the VAT on medicines, we believe this would be a positive way to improve the affordability of medicines. This is particularly important for low-income groups which could be disproportionately affected by a policy to restrict prescribing practices.

5.2.6 The most significant cost savings could be realised by reducing the number of GP appointments and A&E visits used by people with self-treatable conditions, freeing up clinician time as well as reducing the number of prescriptions issued. We do not believe that this will be achieved by restricting prescribing in isolation. People will still want to ask for advice if they have not experienced a particular set of symptoms before. PAGB research in 2016 found that 47% of people would not go to the pharmacist for advice, with one in five of those saying that they didn't think pharmacists were as qualified as doctors[18]. We have called on the NHS to launch a national campaign to promote the expertise of pharmacists to support people with self-treatable conditions. This could be along the lines of the Stay Well This Winter campaign in partnership with pharmacy organisations and industry. In addition, NHS 111 algorithms should be reviewed to ensure more people are being appropriately referred to a pharmacy, so when people do the right thing and phone for advice, they are not unnecessarily directed back to the GP or A&E.

5.2.7 Pharmacists also need to be given the tools to enable them to play a greater role in supporting self care, including giving them "write" access to people's care records and enabling them to refer customers to other healthcare professionals when they see a 'red flag' symptom.

5.2.8 Finally, more needs to be done to improve health literacy at a population level, support people to live healthy lifestyles and prevent ill health. Self care campaigns such as Stay

[18] PAGB, Self Care Nation report. Survey of 5,011 UK adults. Published November 2016 https://www.pagb.co.uk/latest-news/report-self-care-nation-self-care-attitudes-behaviours-uk/

Well This Winter and One You need to be continued and expanded. Health education needs to be included in a meaningful way into the school curriculum for ages 5 to 18 so children grow up understanding how to use NHS services appropriately. The higher education and professional training curriculum for GPs and other health professionals also needs to include self care and methods of supporting people to self care.

5.2.9 PAGB supports the Self Care Forum, a charity which aims to further the reach of self care and embed it into everyday life. The Self Care Forum has a number of resources that could be used and built upon within a national strategy for self care, for example a series of factsheets for healthcare professionals to use when an individual presents with a self-treatable condition[19]. PAGB produces the OTC Directory of self care products for self-treatable conditions which healthcare professionals can use to recommend over-the-counter products[20].

5.3 Ability to realise savings

5.3.1 Taking a system-wide approach to self care (as outlined in 5.2) has the potential to release greater efficiency savings than those outlined in the consultation document.

5.3.2 The premise of the consultation is that if a prescription is not provided the individual will go and purchase the medicine, but there could be a number of unintended consequences if that premise is incorrect.

- The individual could return to the GP a few days later with the same problem
- The individual could go to another GP or A&E to try and obtain a prescription
- The individual could put pressure on the healthcare professional to prescribe an alternative, potentially more expansive medicine
- The individual could leave their condition untreated resulting in more time off work or an exacerbation of their condition such that it requires a more serious intervention further down the line
- The individual could be forced to compromise on the treatment they take or quantity of medicine they use which could lead to inadequate symptom management.

5.3.3 If NHS England and NHS Clinical Commissioners have data that shows what people do if their GP does not provide a prescription, we request this be published. If this data has not been collected, we would recommend an assessment is carried out to determine the potential impact of the possible unintended consequences (as outlined above) should people not self-treat, particularly in relation to conditions that aren't self-limiting.

5.3.4 In France in 2006 the reimbursement rate for a number of medicines was reduced. This resulted in a 50% reduction in the number of prescriptions for those medicines. As a result, there was a 33% increase in the amount of these medicines purchased over-the-counter, but this was still significantly less than the reduction in prescribed items. The data shows an additional eight million medicines were purchased over-the-counter in 2006 than 2005, but this was compared to 115 million fewer medicines being prescribed[21]. Data available does not offer an explanation as to why the majority of people did not purchase the medicines they could no longer be prescribed. However, it is important to recognise the French economy and French regulatory system for over-the-counter medicines is very

[19] Self Care Forum factsheets http://www.selfcareforum.org/fact-sheets/
[20] OTC Directory https://www.pagb.co.uk/self-care/self-care-products-2/
[21] Les Études De La Mutualité Française Sur Le Médicament. Impact économique de la modification des conditions de reimboursement des SMRi en 2006. http://referentiel.nouvelobs.com/file/650/310650.pdf Translated September 2017.

different to the UK, notably there is no GSL category in France and people can only buy medicines from a pharmacy.

5.4 Over-the-counter medicines

5.4.1 The vast majority of medicines classified as a Pharmacy only (P) medicine or for general sale in pharmacies and other retail outlets (GSL) are very clearly labelled to be for **mild to moderate symptoms** and for **short-term use only**. This is the basis upon which the regulator approves their licence as an over-the-counter medicine. The definition of short term may vary for different conditions (for example short-term use for an over-the-counter codeine analgesic for moderate pain is three days, but for an over-the-counter PPI medicine for heartburn, short-term means up to 14 days) and over-the-counter medicines advise people to consult a healthcare professional if their symptoms persist.

5.4.2 This is an important consideration when looking at prescriptions beyond those that are defined as minor and self-limiting to "medicines that are used for longer term, chronic conditions but which are being prescribed at an estimated cost of £545 million per year" (p 26 of consultation). Purchasing and using these medicines for long-term conditions, by definition, goes beyond the licence of over-the-counter medicines as they are being used for longer than the duration that would be advised on the pack and in the patient information leaflet. People know they should not use OTC medicines for longer than advised in the instructions, therefore would need the advice of a healthcare professional, and arguably a prescription, to take these medicines for longer or at higher doses.

5.5 Do you agree with our proposed criteria to assess items for potential restriction

5.5.1 PAGB has strong concerns about the assessment criteria outlined on p26 (and also on p6-7) of the consultation document. We do not believe that **efficacy** and **safety** should appear on this list and request these criteria be removed. Inclusion of safety and efficacy in this list undermines the EU/UK medicines licensing regime. Over-the-counter medicines on the market in the UK have demonstrated clear evidence of a good safety profile, efficacy to treat the condition it is indicated for and suitability for self care. Any suggestion that medicines available to buy in the UK are not safe or efficacious is unhelpful and potentially dangerous. Any concerns about the safety of medicines should be addressed through existing MHRA processes and not conflated with this policy proposal.

5.5.2 Patent protection is also not relevant as a criterion for over-the-counter medicines; PAGB is not aware of any over-the-counter medicines currently on the market in the UK with a patent running.

5.6 Are there individual products, which are either clinically ineffective or available over-the-counter which should be prioritised for early review?

5.6.1 No.

5.7 Evaluation

5.7.1 PAGB would recommend any prescribing restrictions first be trialled in a pilot area to allow for a full evaluation of the impact and potential savings. If the pilot evaluates positively, a phased approach should be taken towards any future roll out.

5.7.2 We would recommend that an evaluation should include an analysis of prescribing before and after to identify changes in practice, quantitative analysis from conversations with GPs

and pharmacists in the pilot area and quantitative analysis of people impacted to determine what course of action they took if the GP did not prescribe for their condition.

6. Concluding remarks

6.1 PAGB is concerned that NHS England and NHS Clinical Commissioners are missing an opportunity to empower people to self care in a sustainable way that will lead to a reduction in GP appointments and A&E visits for self-treatable conditions, as well as making savings on the prescription bill. Increasing people's capacity to look after their own health and wellbeing and reducing their dependence on NHS services for conditions which can be self-treated with the advice of a community pharmacist has the potential to release more than £2 billion of efficiency savings. A system-wide approach is needed.

6.2 A national strategy for self care is required to provide the leadership and policy coordination to implement a range of measures to better equip people to self care. If prescribing restrictions are introduced, the implementation should be timed to first allow other self care initiatives to be embedded first.

6.3 The founding principles of the NHS, *'available to everyone, free at the point of delivery, based on clinical need not the ability to pay'* are important and should be protected. Any change in the prescribing practice for OTC medicines needs to be implemented in a way that does not undermine this and this should not be the first step towards a healthcare system in which only those that can afford to pay can access the treatment they need.

6.4 We would welcome the opportunity to work with NHS England and NHS Clinical Commissioners as these proposals are developed.

John Smith
Chief Executive
PAGB

5 October 2017

About PAGB

PAGB (Proprietary Association of Great Britain) is the UK trade association which represents the manufacturers of branded over-the-counter medicines, self care medical devices and food supplements. For more information about PAGB and its member companies, please see: https://www.pagb.co.uk/about-us/

For further information, please contact:
Donna Castle, Director of Public Affairs and Communications
PAGB, Vernon House, Sicilian Avenue, London, WC1A 2QS
Email: donna.castle@pagb.co.uk
Telephone: 0207431 9315