Items which should not routinely be prescribed in primary care: A consultation on guidance for CCGs
Royal Pharmaceutical Society response

1. In what capacity are you responding?
Organisation: The Royal Pharmaceutical Society

2. Have you read the document Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs?
Yes

3. Equality and Health Inequalities
NHS England has legal duties which require giving due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and having regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities. An initial Equality and Health Inequalities Assessment (EHIA) has been carried out on these proposals and this can be read here. Further information on our duties can be read at https://www.england.nhs.uk/about/equality/

3.1 Do you feel there are any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?
In addition to the groups protected by the Equality Act 2010 people who cannot afford to pay for medicines available over the counter will be disproportionately affected by this work.

In your 'Equality and Health Inequalities –Full Analysis - Items which should not be routinely prescribed in primary care' document on page 8 you state that "There is no routinely collected data on prescribing and disability so we cannot definitively assess fully at a national level. Studies have identified that people with disability are more likely to suffer from chronic pain however it is unknown if this is applicable to the population taking the medications within the review." We believe that the proposal to restrict access to OTC medicines could adversely affect those with disabilities.

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

Yes, evidence should be obtained to clarify the impact on people on low incomes if OTC products are no longer able to be supplied on the NHS. If people are unable to access such products this could lead to greater health inequalities and also worsening health outcomes.

3.3 How will the guidance be updated and reviewed?
Thinking about the process for future update and review of the guidance:
How do you feel about the proposed process for identification of items for possible addition to the guidance or indeed possible removal, from the guidance?
Unsure, please see below

If needed, please provide further information
Having been involved in the NHS England working group we are concerned about the lack of patient engagement prior to initial options for change being developed. There are no patient representatives on the working group and we would recommend that National Voices, Patient's Association and Healthwatch England are invited onto the group. There should be significantly more engagement with patients who may be affected by the recommendations made in this and future guidance.

There needs to be more engagement with local authorities and hospitals as this is not just a primary care issue.

Section 4: Proposals for CCG commissioning guidance

We have reviewed the recommendations for the 18 products identified in section 4 and have summarised our comments below.

Co-Proxamol
There are significant patient safety concerns related to the use of co-proxamol, it has been removed from the BNF, and there are alternatives available for prescribers to use.
We support the recommendation.

Dosulepin
After speaking to our members we have heard that a very small proportion of patients (c.a. 1 in 25,000) would benefit from the continued availability of this treatment, in particular the 25mg dosage, providing prescribers take a managed approach to known risks and side effects. The vast majority of these patients are elderly and compliant with their current medication and could face the possibility that any switch may not be well tolerated. This in turn could result in increased resource and costs to the NHS. We would suggest that a more realistic approach would be to see the prescribing of Dosulepin being gradually phased over a period of time.

Prolonged-release Doxazosin
We support the recommendation

Immediate Release Fentanyl

NICE guidance recommends the use of oral immediate release morphine as first line rescue medication of breakthrough pain so we support the recommendation.

Glucosamine and Chondroitin
There is limited clinical data regarding the effectiveness of these products for the treatment of osteroarthritis and it is also readily available to purchase for patients who chose to supplement their treatment in this way.
We support the recommendation.

Herbal Treatments
There is limited evidence regarding the effectiveness of such products and they are extensively available to purchase as an option for patients to consider on a cost / benefit basis.
We support this recommendation

Homeopathic Treatment.
The RPS does not endorse homeopathy as a form of treatment because there is no scientific basis for homeopathy nor any evidence to support the clinical efficacy of homeopathic products beyond a placebo effect. We do not support the prescribing of homeopathic products on the NHS.
We support this recommendation

Lidocaine Plasters
A number of our members have said they have seen patients benefit from the supply of these plasters for the relief of neuropathic pain and these are routinely used in hospitals for complex patients. The plasters offer the benefit of being cut in accordance with patient requirements and because of the nature of the presentation offer better control of active release and are less messy, thereby aiding patient compliance.
Lidocaine plasters should be prescribed based on patient need

Liothyronine
Some patients may be unable to convert their T4 to T3 through the pituitary pathway and would require to be treated with liothyronine which is a T3 drug. Most thyroid treatment is in the form of T4 which is naturally converted to T3 in the body but it is sometimes difficult to replicate the natural balance in the body when taking the tablet form. Because of the different metabolic responses seen in patients and the effect this has on their feeling of wellbeing, general health, activity levels and symptoms, it is important to understand the metabolic relationship that exists in individual patients. In essence if the pituitary doesn't convert T4 to T3 or if metabolic pathway is impaired in some way then liothyronine treatment may be necessary or alternatively giving higher doses of T4 which is not without its own health risks.
If patients remain unwell on traditional thyroid treatment and the T3 version is unavailable there could be a cost to the system which outweighs the cost of the medication.
We are also aware that liothyronine can be used as an adjunct in resistant depression and this is mentioned in the Maudsley guidelines.
We do not support this recommendation as the effectiveness of this medicine is well established and costs of medicines can fluctuate based on a variety of factors such as supply chain issues due to stock shortages. We recommend that a mechanism is established whereby prescribers clarify their reason for prescribing this particular product.

Lutein and Antioxidants
These products are readily available to purchase for patients who chose to supplement their treatment in this way.
We support this recommendation

Omega-3 Fatty Acid Compounds
These products are readily available to purchase for patients who chose to supplement their treatment in this way.
We support this recommendation

Oxycodone and Naloxone Combination Products
We support this recommendation

Paracetamol and Tramadol Combination Products
We support this recommendation

Perindopril Arginine
We support this recommendation.

Rubefacients (excluding topical NSAIDs)
This products are available to purchase for patients who chose to supplement their treatment in this way.
We support this recommendation

Once Daily Tadalafil
We support this recommendation

Travel Vaccines
We support this recommendation

Trimipramine
Members have told us that a small group of patients (c.a. 1 in 60,000) would benefit from availability and continuation of such treatment where their condition has not responded well to prescribed SSRI's (the recommended first line treatment). Although trimipraine is usually used to treat depression, insomnia or chronic pain; it is also helpful in managing withdrawal from alcohol or narcotics. Clinically the drug is a strong antidepressant with strong antianxiety effects and it does not interfere with normal sleep patterns. It works on norepinephrine more than on serotonin and dopamine (the neurotransmitters most likely to be involved in causing depression) and in that respect we consider it provides a useful additional tool in the treatment of such mental health conditions.
We do not support the recommendations made and would suggest that a more realistic approach would be to see the prescribing of trimipramine being gradually phased out over a period of time.

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

In relation to section 5 we are strongly opposed to making these products unavailable via the NHS. This move would fundamentally alter the principle that care is free at the point of delivery and as such should be legislated for by Parliament and not implemented by Clinical Commissioning Groups. Principle 2 of the NHS Constitution clearly states that ***'Access to NHS services is based on clinical need, not an individual's ability to pay. NHS services are free of charge, except in limited circumstances sanctioned by Parliament.'*** Such a move would further increase inequalities in relation to medical conditions and socio-economic status and will increase risks to patient's health. These proposals would not only adversely affect a patient's health and care, but also consequently target and potentially discriminate against people with long-term conditions, patients with multimorbidities, the young, cancer sufferers, the elderly and the poorest in society. Whilst we recognise the NHS needs to operate within its budget allocated by government, as proposals currently stand, we could not support health professionals being asked to restrict access to cost-effective treatment.

We do recognise the need to encourage people to move towards self-care, and to purchase self-care treatments when they are able to do so. We support and encourage our members to empower patients to self-care. We also support the need to provide consistency across the country and are aware that some CCGs have already restricted access to some PTC medicines. We know that people may visit their GP to get a prescription for a product that can be purchased from a pharmacy so that they can obtain the product free of charge. We recommend that GPs and practice staff are encouraged to refer patients with minor ailments to their local pharmacy where local minor ailment services are in place. Community pharmacists are ideally placed to support patients to self-care and RPS continues to advocate for an NHS Minor Ailments service. Such a service will also help to reduce pressure on GPs and A&E. Research demonstrates that there are 57 million GP appointments and 3.7 million visits to A&E each year for self-treatable conditions which people could have asked a pharmacist for advice about. These could have been successfully treated with an OTC medicine and make estimated cost-savings of £2.3 billion a year[1],[2].m Other evidence demonstrates that if community pharmacists were commissioned to provide a common ailment service nationwide, the NHS could save £1.1 billion each year[3].

We are concerned about the term 'low clinical value' that is used in this consultation in relation to the OTC medicines. Many of these products listed are clinically effective such as head lice treatment or treatment for athlete's foot. The current situation in the NHS means patients have a choice to either obtain the product on the NHS via their GP or via a local minor ailment scheme, or purchase their product from the pharmacy. We understand that this puts additional pressure on general practice and in order to relieve that burden the products should be available on the NHS via another supply route. We do not think that using the time of a GP to prescribe medicines readily available over the counter from a highly trained and competent pharmacy professional is appropriate. There is an opportunity to develop services in primary care utilising the skills of community pharmacists to support patients who do not have the means to purchase these

[1] https://www.pagb.co.uk/content/uploads/2016/06/Driving-the-self-care-agenda-AndyTisman.pdf
[2] https://www.pagb.co.uk/content/uploads/2016/06/PAGB_AE_Executive_Summary_June-2015.pdf
[3] http://www.pharmacyresearchuk.org/our-research/our-projects/the-minor-ailment-study-mina/

products. A report in 2016 explored the non-supply of OTC products to people seeking self-care. Data was collected from 5,035 community pharmacies, including seven of the largest national multiple pharmacy chains, six regional independent multiples (together representing 250 branches) and 95 independent pharmacies. Over the one-week period, pharmacies recorded a total of 113,278 instances where pharmacy teams used their professional judgement to support a decision not to supply a requested OTC product to a patient/customer. Through cautious extrapolation, this suggests that, on average, community pharmacy teams in England choose not to supply a requested OTC product over 13 million times per annum.

Making these OTC products unavailable on the NHS could have unintended consequences in terms of increased costs to the NHS due to

- Patients being admitted to hospital with conditions such as faecal impaction, simply because their GP was unable to prescribe laxatives and they could not afford to purchase them.
- Patients unable to gain access to licensed treatments on the NHS in primary care could place increased pressures on A&E services, increasing downstream costs for the NHS and impacting patients' outcomes.
- Patients not taking any treatment for their condition as they cannot afford to purchase it which may lead to public health issues as well as impacting on primary care and A&E services as above
- Patients feeling as if they cannot talk about minor ailments to healthcare professionals as it is something they should treat themselves and this could result in more serious underlying conditions being missed.
- Prescribers feeling pressurised to step up treatment inappropriately where they are aware that patients will not be able to afford to buy the appropriate OTC medicine they would have otherwise been able to prescribe. This also has the potential to harm patient outcomes.

It would be extremely difficult to distinguish between medicines used to treat a condition that is considered to be self-limiting and quickly cured and those intended for longer term use as a consequence of a patient's medical condition or managing short or known side effects of other medicines they have to take. Pharmacists working in the community have been underestimated as they undertake such consultations on a daily basis and provide appropriate advice, and where necessary, supply of required treatment. (opiod analgesic treatment only supplied for max 3 days)

At Expo 2017 it was stated that Simon Stevens " *unveiled new plans to free up funds for the latest world class treatments by slashing hundreds of millions from the nation's drugs bill and announced that new and cutting edge treatments will be routinely available for the first time. This will include revolutionary new treatment for Hepatitis C, new measures to slash up to another £300 million from the nation's medicines bill, trailblazing new treatment to restore sight, routine commissioning of the latest technology to help deaf children hear, and an expansion of the Test Bed programme that is testing the treatments and care models of tomorrow.* It appears that the decision to require patients to purchase much needed over the counter treatments rather than receive them via the NHS, has already been made. A recent article in GP Online states that '*A total of 17.8m items in categories likely to be heavily affected by a ban on prescribing drugs available OTC were prescribed*

by GPs over the three months from April to June this year - meaning around 71m could be prescribed across a full year. The 71m items prescribed came at a cost of £346m to the NHS'.

Prior to the development of any further policy options, a full impact assessment should be carried out in consultation with patient and professional groups to clarify the consequences of restricting access to these products via the NHS. This should be made publically available and must include the impact on patients and the public and not just focus on the cost savings to the NHS.

Rather than making OTC medicines unavailable via the NHS, we suggest that more effort is used to embed self-care into the NHS and people's lives including actions to improve health literacy and support to help people live healthier lives. We recognise this is a complex issue and would require a system wide approach and an overarching national strategy. Educating people about self care and the benefit it can have both to themelves and the NHS could go a long way to reducing prescribing and supply of OTC medicines without the need to introduce restrictions.

Sandra Gidley, Chair, English Pharmacy Board

About us

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

Leadership, representation and advocacy: Ensuring the expertise of the pharmacist is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists deliver excellent care and also to advance their careers through professional advancement, career advice and guidance on good practice.

Professional networking and publications: hosting and facilitating a series of communication channels to enable pharmacists to discuss areas of common interest, develop and learn.