

Response ID ANON-788X-REJF-6

Submitted to **Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs**
Submitted on 2018-03-12 16:44:18

Introduction

1 In what capacity are you responding?

In what capacity are you responding?:

Professional Representative Body

If 'other' please specify::

2 Name or organisation (optional):

Name or organisation:

The Royal Pharmaceutical Society

3 Email address (optional):

Email address (optional):

andrew.cooke@rpharms.com

4 Have you read the document 'Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs'?

Yes

Equality and Health Inequalities

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

Yes

Age

Please provide further information on why you think this might be the case::

Yes, 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. 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.

6 Do you feel there is any further evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups?

Yes

Please provide further information on why you think this might be the case::

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.

Proposals for CCG commissioning guidance

7 Do you agree with the three proposed categories for [items] or [conditions] as follows:

How do you feel about the three proposed categories for [items] or [conditions] as follows: - An item of low clinical effectiveness, where there is a lack of robust evidence for clinical effectiveness.:

Neither agree or disagree

How do you feel about the three proposed categories for [items] or [conditions] as follows: - A condition that is self-limiting and does not require medical advice or treatment as it will clear up on its own.:

Neither agree or disagree

How do you feel about the three proposed categories for [items] or [conditions] as follows: - A condition that is a minor illness and is suitable for self-care and treatment with items that can easily be purchased over the counter from a pharmacy.:

Neither agree or disagree

Please provide further information::

The RPS has strong concerns around restricting the access to OTC products as we believe that this goes against the NHS constitution which very clearly states

that patients should have access to treatment based on clinical need and not the ability to pay. In addition, many of the items included in this OTC consultation are effective and therefore have clinical value. However, if this were to go ahead then we would agree with the categories above. For the third category (A condition that is a minor illness and is suitable for self-care and treatment with items that can easily be purchased over the counter from a pharmacy), any guidance must be cognisant of the licensing restrictions on many items, which preclude sale. Pharmacists can only sell medicines within their licensed indications.

General exceptions

8 Do you agree with the general exceptions proposed?

How do you feel about the general exceptions proposed? - Circumstances where the product licence doesn't allow the product to be sold over the counter to certain groups of patients.:

Agree

How do you feel about the general exceptions proposed? - Patients with a minor condition suitable for self-care that has not responded sufficiently to treatment with an OTC product.:

Agree

How do you feel about the general exceptions proposed? - Patients where the clinician considers that the presenting symptom is due to a condition that would not be considered a minor ailment.:

Agree

How do you feel about the general exceptions proposed? - Circumstances where the prescriber believes that in their clinical judgement, exceptional circumstances exist that warrant deviation from the recommendation to self-care.:

Agree

How do you feel about the general exceptions proposed? - Patients where the clinician considers that their ability to self-manage is compromised as a consequence of social, medical or mental health vulnerability to the extent that their health and/or wellbeing could be adversely affected if left to self-care.:

Neither agree or disagree

Please provide further information::

We agree with the exemptions proposed but would suggest an addition as below.

Also, the overarching statements under 1.5 paragraphs 2, 3 and 4 should be highlighted and made more prominent as these are the conditions in which prescribers should definitely continue to prescribe OTC products.

Further exceptions

9 Should we include any other patient groups in the general exceptions?

Yes

Please provide further information::

We have concerns around a person's ability to pay for products and although there is a general exemption on vulnerability we think the word financial should be included in this exemption to strengthen the fact that, particularly in deprived areas, the ability to pay needs to be taken into consideration. So the revised exemption would be 'Patients where the clinician considers their ability to self-manage is compromised as a consequence of social, medical, financial or mental health vulnerability to the extent that their health and/or wellbeing could be adversely affected if left to self-care.'

However, we also have concerns about how such vulnerability will be assessed and the additional onus this may place on prescribers.

Drugs with limited evidence of clinical effectiveness

10 Do you agree with the recommendation to: Advise CCGs to support prescribers in advising patients that [item] should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness?

How do you feel about the recommendation to: Advise CCGs to support prescribers that the following items should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness? - Probiotics.:

Agree

How do you feel about the recommendation to: Advise CCGs to support prescribers that the following items should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness? - Vitamins and minerals.:

Neither agree or disagree

Please provide further information::

The RPS has strong concerns around restricting the access to OTC products as we believe that this goes against the NHS constitution which very clearly states that patients should have access to treatment based on clinical need and not the ability to pay. In addition, many of the items included in this OTC consultation are effective and therefore have clinical value. We request to see the outcomes of any legal advice that has been sought and provided. Patients with a vitamin or mineral deficiency should be exempt.

Self-limiting conditions

11 Do you agree with the recommendation to: Advise CCGs to support prescribers in advising patients that a prescription for treatment of [condition] should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment?

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Acute sore throat.:

Agree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Cold sores.:

Agree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Conjunctivitis.:

Neither agree or disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Coughs and colds and nasal congestion.:

Agree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Cradle cap (Seborrhoeic dermatitis – infants).:

Agree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Haemorrhoids.:

Neither agree or disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Infant colic.:

Agree

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Mild cystitis.:

Neither agree or disagree

Please provide further information::

The RPS has strong concerns around restricting the access to OTC products as we believe that this goes against the NHS constitution which very clearly states that patients should have access to treatment based on clinical need and not the ability to pay. In addition, many of the items included in this OTC consultation are effective and therefore have clinical value. We would be interested in the outcomes of any legal advice that has been sought and provided.

We agree with the conditions listed, other than:

Conjunctivitis: where a treatment is needed, either an exception is required regarding restrictions on sale for young children, pregnant mothers etc, or a change in the OTC license

Haemorrhoids: Persistent anal bleeding should be referred to a GP

Mild Cystitis: Using the term 'mild' risks unwarranted variation due to individual interpretation. Greater clarity is required, including whether this relates only to women.

Minor ailments suitable for self- care

12 Do you agree with the recommendation to: Advise CCGs to support prescribers in advising patients that a prescription for treatment of [condition] should not routinely be offered in primary care as the condition is appropriate for self-care?

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Contact dermatitis.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Dandruff.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Diarrhoea (Adults).:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Dry eyes/sore (tired) eyes.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Earwax.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Excessive sweating (Hyperhidrosis).:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Head lice.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Indigestion and heartburn.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Infrequent constipation.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Infrequent migraine.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Insect bites and stings.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mild acne.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mild dry skin/sunburn.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mild to moderate hay fever/seasonal rhinitis.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Minor burns and scalds.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Minor conditions associated with pain, discomfort and/fever. (e.g. aches and sprains, headache, period pain, back pain).:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mouth ulcers.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Nappy rash.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Oral thrush.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Prevention of dental caries.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Ringworm/athletes foot.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Teething/mild toothache.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Threadworms.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Travel sickness.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Warts and verrucae.:

Disagree

Please provide further information::

The RPS has strong concerns around restricting the access to OTC products as we believe that this goes against the NHS constitution which very clearly states that patients should have access to treatment based on clinical need and not the ability to pay. In addition, many of the items included in this OTC consultation are effective and therefore have clinical value.

Throughout this section the term 'mild' is used and we believe there are risks to using this term as it is open to interpretation and will very much depend on how it is marketed to the public. And in addition mild dry skin can become severe quite quickly, particularly in children.

Exceptions for each should include: 'in accordance with the guidance on NHS Choices, when to get medical advice'

Condition specific exceptions

13 Are there any item or condition specific exceptions you feel should be included, in addition to those already proposed and the general exceptions covered earlier?

Yes

Please provide further information::

Guidance should be produced for GPs to help them understand the licensing around OTC products and the fact that many of them are not licensed for recurrent use. This guidance should be produced nationally by NHS England. NHS England should also support a review of OTC license changes to reflect this guidance

We are concerned around the impact of this guidance on locally commissioned Minor Ailment Schemes via community pharmacies and although the continued commissioning of such schemes will be down to local CCGs, we believe that this warrants mentioning in the document as it will be a question that will be asked. It could be included and discussed in the unintended consequences section.

Under section 1.1 paragraph 5 starting 'The costs to the NHS' adds little to the guidance document and could be removed

Under section 1.2 the final paragraph states that funding saved from not prescribing OTC products can be reinvested into patient care but the likelihood is that they will in fact be used to plug CCG deficits and this should be reflected in this paragraph.

In Appendix 2 there is a mixture of individual products and formulations for different conditions which is not particularly helpful.

The RPS is strongly opposed to making OTC products, related to these conditions, 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 multi-morbidities, 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 OTC 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 a nationally commissioned 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 year¹. Other evidence demonstrates that if community pharmacists were commissioned to provide a minor ailment service nationwide, the NHS could save £1.1 billion each year².

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 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.

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'.

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 themselves and the NHS could go a long way to reducing prescribing and supply of OTC medicines without the need to introduce restrictions.

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/>