Bruce Warners (NHS England) and Graham Jackson (NHS Clinical Commissioners)
Co-chairs of the joint clinical working group
Medicines, Diagnostics and Personalised Medicine Unit
NHS England
22 London Road
London SE1 6JW

Sent via email: england.medicines@nhs.net

Ref: Items which should not be routinely prescribed in primary care consultation – BMA 19/10/17

19 October 2017

Dear Mr Warners and Mr Jackson

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

The British Medical Association (BMA) is an apolitical professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care. We have a membership of over 170,000, which continues to grow every year.

The Association welcomes the opportunity to respond to the consultation on guidance for CCGs for items which should not be routinely prescribed in primary care. Please find enclosed our submission, and we have also submitted our comments on line.

The BMA’s response addresses key questions listed in the consultation document. We hope that our submission is useful – please do not hesitate to contact us for more information if required.

Yours sincerely

Angela Kyle
Head, Committee Services
Policy Directorate
Consultation questions

**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/](https://www.england.nhs.uk/about/equality/)

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

Patients with a disability will be disproportionately affected by the proposal to stop prescribing of items available over-the-counter (OTC), and may not be able to obtain the medicines that they need. Pregnant women are among one of the groups who are currently entitled to free prescriptions and all of these will be adversely affected by restrictions on OTC medicines.

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, patients on low incomes will be disproportionately affected by the proposal to stop prescribing of items available over-the-counter, and may not be able to obtain the medicines that they need.

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

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?

We do not have a specific view on this.
Section 4: Proposals for CCG commissioning guidance

4.1 Co-proxamol

| Background | Co-proxamol was a pain-killer which was previously licensed in the UK until being fully withdrawn, in 2007, from the market due to safety concerns. All use in the UK is now on an unlicensed basis. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate co-proxamol for any new patient  
• Advise CCGs to support prescribers in deprescribing co-proxamol in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for co-proxamol to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional |

Do you agree with the proposed recommendations for Co-proxamol?

We disagree with third bullet point only. Due to its toxicity, we believe that co-proxamol should either be placed on the blacklist of drugs unavailable on the NHS or be restricted to specialist prescription only.

4.2 Dosulepin

| Background | Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Dosulepin for any new patient  
• Advise CCGs to support prescribers in deprescribing Dosulepin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for Dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional |

Do you agree with the proposed recommendations for Dosulepin?

We disagree with third bullet point only. Any decision to seek advice from other health care professionals will depend on individual doctor and patient factors and should not be a requirement for ongoing prescribing. Consideration should be given as to whether this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.
4.3 Prolonged-release Doxazosin

| Background | Doxazosin is an alpha-adrenoceptor blocking drug that can be used to treat hypertension and benign prostatic hyperplasia. There are two oral forms of the medication (immediate release and prolonged-release) and both are taken once daily. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Prolonged-release Doxazosin for any new patient  
• Advise CCGs to support prescribers in deprescribing Prolonged-release Doxazosin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for Prolonged-release Doxazosin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professionals. |

Do you agree with the proposed recommendations for Prolonged-release Doxazosin?

We disagree with third bullet point only. Any decision to seek advice from other health care professionals will depend on individual doctor and patient factors and should not be a requirement for ongoing prescribing. Where changes to a patient’s treatment are made for reasons of cost efficiency only (i.e. with no clinical or safety gain for the patient) full resources need to be provided for the practice to enable this to happen without compromising the care offered to other patients.

4.4 Immediate Release Fentanyl

| Background | Fentanyl is a strong opioid analgesic. It is available as an immediate release substance in various dosage forms; tablets, lozenges, films and nasal spray. Immediate release fentanyl is licensed for the treatment of breakthrough pain in adults with cancer who are already receiving at least 60mg oral morphine daily or equivalent. This recommendation does not apply to longer sustained release versions of fentanyl which come in patch form. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Immediate Release Fentanyl for any new patient  
• Advise CCGs to support prescribers in deprescribing Immediate Release Fentanyl in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for Immediate Release Fentanyl to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional. |
Do you agree with the proposed recommendations for Immediate Release Fentanyl?

We disagree with the proposals over immediate release fentanyl.

For terminally ill patients being cared for in the community, immediate release fentanyl is an extremely effective analgesic that can be given by family members. Patients with bone metastases can experience sudden severe pain on movement and for the family at home immediate analgesia is essential. Its mode of action is much more rapid than oral morphine and this avoids the need to teach families how to administer morphine or diamorphine by injection, which they find a difficult and burdensome role to take on. The availability of immediate analgesia may avoid unnecessary hospital admission.

We fully recognise that there has been a number of deaths in Northern England associated with the illicit use of this drug and we would support reduction in availability (although we are not aware whether the supplies were obtained from NHS sources or not in these cases). We would suggest that immediate release fentanyl is classified as an ‘amber’ drug suitable for prescribing in primary care only for palliative patients under formal shared care arrangements.

We have raised concerns previously about pain management in end of life care and have specifically recommended that “Systems need to be in place, in all areas, to ensure appropriate and timely availability of medication and equipment, particularly for those being cared for in the community.”

4.5 Glucosamine and Chondroitin

<table>
<thead>
<tr>
<th>Background</th>
<th>Glucosamine and Chondroitin are nutraceuticals which used to improve pain associated with osteoarthritis.</th>
</tr>
</thead>
</table>
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Glucosamine and Chondroitin for any new patient  
• Advise CCGs to support prescribers in deprescribing Glucosamine and Chondroitin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. |

Do you agree with the proposed recommendations for Glucosamine and Chondroitin?

We disagree and this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

---

4.6 Herbal Treatments

| Background | In the UK, the MHRA allows herbal products to be marketed for minor health conditions that don’t require medical supervision, upon receipt of a traditional herbal registration (MHRA detailed guidance) |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate herbal items for any new patient  
• Advise CCGs to support prescribers in deprescribing herbal items in all patients and where appropriate, ensure the availability of relevant services to facilitate this change |

Do you agree with the proposed recommendations for herbal treatments?

We disagree and this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

4.7 Homeopathy

| Background | Homeopathy seeks to treat patients with highly diluted substances that are administered orally. (MHRA detailed guidance) |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate homeopathic items for any new patient  
• Advise CCGs to support prescribers in deprescribing homeopathic items in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. |

Do you agree with the proposed recommendations for homeopathy?

We disagree and this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

The BMA has longstanding policy (since 2010) calling for the removal of prescribing of homeopathic preparations being funded by the NHS:

“That this Meeting believes that, in the absence of valid scientific evidence of benefit:  
(i) there should be no further commissioning of, nor funding for, homeopathic remedies or homeopathic hospitals in the NHS;  
(ii) no UK training post should include a placement in homeopathy;  
(iii) pharmacists and chemists should remove homeopathic remedies from shelves indicating they are ‘medicines’ of any description, and place them on shelves clearly labelled ‘placebos’
4.8 Lidocaine Plasters

| Background | Lidocaine plasters can be applied for pain relief and are licensed for symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Lidocaine plasters for any new patient  
• Advise CCGs to support prescribers in deprescribing lidocaine plasters in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for lidocaine plasters to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multidisciplinary team and/or other healthcare professional |

Do you agree with the proposed recommendations for Lidocaine Plasters?

We disagree with the recommendations as it would be inappropriate to deprescribe in patients who had had a good therapeutic response to treatment and where other treatments had not been effective. Where changes to a patient’s treatment are made for reasons of cost efficiency only (i.e. with no clinical or safety gain for the patient) full resources need to be provided for the practice to enable this to happen without compromising the care offered to other patients.

With the increasing number of patients with mesothelioma or other serious pathology causing neuropathic pain, topical lidocaine can provide an effective and safe adjunct in analgesia. Lidocaine plasters are also recommended by PrescQIPP for post herpetic neuralgia in certain circumstances.

We would expect this item to become more cost-effective with expected price changes.

4.9 Liothyronine

| Background | Liothyronine (sometimes known as T3) is used to treat hypothyroidism. It has a similar action to levothyroxine but is more rapidly metabolised and has a more rapid effect. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Liothyronine for any new patient  
• Advise CCGs to support prescribers in deprescribing Liothyronine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for Liothyronine to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multidisciplinary team and/or other healthcare professional |

Do you agree with the proposed recommendations for Liothyronine?

We disagree with the third bullet point only. Patients currently taking Liothyronine have complex endocrine needs and should be under the care of a consultant who should be responsible for any deprescribing required. CCGs must support secondary care referral and ongoing prescribing for these patients.

We agree with the statement from the Royal College of Physicians that ‘T3 in the treatment of hypothyroidism should be reserved for use by accredited endocrinologists in individual patients’ and therefore Liothyronine should be classified as a ‘red drug’ and not prescribed in primary care.

4.10 Lutein and Antioxidants

| Background | Lutein and antioxidants (e.g. vitamin A, C E and zinc) are supplements recommended for Age Related Macular Degeneration. A variety of supplements are available to purchase in health food stores and other outlets where they are promoted to assist with “eye health”. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate lutein and antioxidants for any new patient  
• Advise CCGs to support prescribers in deprescribing lutein and antioxidants in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. |

Do you agree with the proposed recommendations for Lutein and Antioxidants?

We disagree with the recommendation. Patients receiving these substances will be doing so on the advice of their ophthalmologist and are understandably going to be very anxious about further reductions in their vision. Over time it is likely that this will occur and when it does they may blame this on the withdrawing of the supplements. For this reason, this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS, to ensure that no harm is done to the doctor/patient relationship.

4.11 Omega-3 Fatty Acid Compounds

| Background | Omega-3 fatty acid compounds are essential fatty acids which can be obtained from the diet. They are licensed for adjunct to diet and statin in type IIb or III hypertriglycerideremia; adjunct to diet in type IV hypertriglycerideremia; adjunct in secondary prevention in those who have had a myocardial infarction in the preceding 3 months. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Omega-3 Fatty Acids for any new patient  
• Advise CCGs to support prescribers in deprescribing Omega-3 Fatty acids in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. |

Do you agree with the proposed recommendations for Omega-3 Fatty Acid Compounds?
We disagree and this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.
4.12 Oxycodone and Naloxone combination product

**Background**
Oxycodone and Naloxone combination product is used to treat severe pain and can also be used second line in restless legs syndrome. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut.

**Recommendation**
- Advise CCGs that prescribers in primary care should not initiate Oxycodone and Naloxone combination product for any new patient
- Advise CCGs to support prescribers in deprescribing Oxycodone and Naloxone combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
- Advise CCGs that if, in exceptional circumstances, there is a clinical need for Oxycodone and Naloxone combination product to be prescribed in primary care, this should be undertaken in cooperation arrangements with a multidisciplinary team and/or other healthcare professionals.

Do you agree with the proposed recommendations for oxycodone and naloxone?
In terminally ill patients who experience severe constipation on opioids, the combination of oxycodone and naloxone can greatly improve their quality of life. When patients are taking many medications already, opioid-induced constipation can prove very difficult to manage and regular quantities of senna liquid combined with magnesium hydroxide, whilst effective, can be burdensome to take and in some patients result in diarrhoea.

We would suggest that Oxycodone and Naloxone combination product should be classified as an 'amber drug' suitable for prescribing in primary care only for palliative patients under formal shared care arrangements.

4.13 Paracetamol and Tramadol Combination Product

**Background**
Paracetamol and Tramadol are both commonly available painkillers. This recommendation relates to where both chemical ingredients are used together in a single combination product.

**Recommendation**
- Advise CCGs that prescribers in primary care should not initiate Paracetamol and Tramadol combination product for any new patient
- Advise CCGs to support prescribers in deprescribing Paracetamol and Tramadol combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Do you agree with the proposed recommendations for Paracetamol and Tramadol Combination product?
We disagree and this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.
4.14 Perindopril Arginine

**Background**
Perindopril is an ACE inhibitor used in heart failure, hypertension, diabetic nephropathy and prophylaxis of cardiovascular events. The perindopril arginine salt version was developed as it is more stable in extremes of climate than the perindopril erbumine salt, which results in a longer shelf-life. The arginine is significantly more expensive than the erbumine salt, for example 28 days supply of Perindopril arginine costs £6.28 versus £1.07 for an equivalent 28 days treatment with perindopril erbumine.

**Recommendation**
- Advise CCGs that prescribers in primary care should not initiate Perindopril Arginine for any new patient
- Advise CCGs to support prescribers in deprescribing Perindopril Arginine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Do you agree with the proposed recommendations for Perindopril Arginine?

We disagree and this would be better dealt with by inclusion in the backlist of drugs unavailable on the NHS.

4.15 Rubefacients (excluding topical NSAIDs)

**Background**
Rubefacients are topical preparations that cause irritation and reddening of the skin due to increased blood flow. They are believed to relieve pain in various musculoskeletal conditions and are available on prescription and in over-the-counter remedies. They may contain nicotinate compounds, salicylate compounds, essential oils and camphor.

**Recommendation**
- Advise CCGs that prescribers in primary care should not initiate Rubefacients (excluding topical NSAIDs) for any new patient
- Advise CCGs to support prescribers in deprescribing Rubefacients (excluding topical NSAIDs) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Do you agree with the proposed recommendations for Rubefacients (excluding topical NSAIDs)?

We disagree with the recommendations. Rubefacients are most often prescribed for chronic musculoskeletal pain in elderly patients. If they are made unavailable it is likely that alternative treatments will be requested. There are few alternative pharmacological options available and these have significant problems in frail patients including confusion, falls and constipation. Any cost savings made will be reduced by increases elsewhere in the drug budget, and may be reversed by increased costs elsewhere in the health and social care systems caused by iatrogenic illness from less-safe alternative prescribing.
4.16 Once Daily Tadalafil

**Background**

Tadalafil is a phosphodiesterase-5-inhibitor and is available in strengths of 2.5mg, 5mg, 10mg and 20mg used to treat erectile dysfunction. In addition 2.5mg and 5mg can be used to treat benign prostatic hyperplasia. Only 2.5mg and 5mg should be used once daily. 10mg and 20mg* are used in a “when required fashion”.

Tadalafil can be prescribed for erectile dysfunction in circumstances as set out in part XVIIIIB of the Drug Tariff.

*There is also a 20mg once daily preparation, branded Adcirca, which is used to treat pulmonary hypertension. This recommendation does not apply to this product, however it should only be prescribed by specialist centres and not routinely prescribed in primary care.

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Advise CCGs that prescribers in primary care should not initiate once daily Tadalafil for any new patient</td>
</tr>
<tr>
<td>• Advise CCGs to support prescribers in deprescribing once daily Tadalafil in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.</td>
</tr>
</tbody>
</table>

Do you agree with the proposed recommendations for Once Daily Tadalafil?

We disagree and this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

4.17 Travel Vaccines

**Background**

Some travel vaccines are available on the NHS and others are not available on the NHS. For travel vaccines not available on the NHS, they are sometimes inappropriately administered for the purposes of travel, due them being available for prevention of illness in other circumstances.

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Advise CCGs that prescribers in primary care should not initiate the stated travel vaccines for any new patient</td>
</tr>
</tbody>
</table>

Do you agree with the proposed recommendations for Travel Vaccines?

The current situation where some travel vaccines can be provided on the NHS and others cannot, is inconsistent and causes confusion for doctors and patients. We would support the introduction of a unified system which is more easily understood providing it aligns with GPs’ contractual obligations.

An analysis must be performed of the potential risks of an increase in imported illnesses should vaccination rates fall.
4.18 Trimipramine

| Background | Trimipramine is a tricyclic antidepressant (TCA) however the price of trimipramine is significantly more expensive than other antidepressants. |
| Recommendation | • Advise CCGs that prescribers in primary care should not initiate Trimipramine for any new patient  
• Advise CCGs to support prescribers in deprescribing Trimipramine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.  
• Advise CCGs that if, in exceptional circumstances, there is a clinical need for Trimipramine to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional |

Do you agree with the proposed recommendations for Trimipramine?

We disagree with third bullet point only. Any decision to seek advice from other health care professionals will depend on individual doctor and patient factors and should not be a requirement for ongoing prescribing. Where changes to a patient’s treatment are made for reasons of cost efficiency only (i.e. with no clinical or safety gain for the patient) full resources need to be provided for the practice to enable this to happen without compromising the care offered to other patients. Consideration should be given as to whether this would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

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

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

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

These criteria are:
- **Legal Status** i.e. is it prescription only, or is it available over the counter in pharmacies and/or any retail outlet?
- **Indication** i.e. what condition is it used to treat?
- **Background** i.e. a general narrative on the drug incl. pack size, tablet size, whether administered orally etc.
- **Patent Protection** i.e. is the drug still subject to a patent?
- **Efficacy** i.e. is it clinically effective?
- **Safety** i.e. is the drug safe?
- **Alternative treatments and exceptionality for individuals** i.e. do alternatives exist and if so, who would they be used for?
- **Equalities and Health Inequalities** i.e. are there groups of people who would be disproportionately affected?
- **Financial implications, comprising:**
  - **Commissioning/funding pathway** i.e. how does the NHS pay for the drug?
  - **Medicine Cost** i.e. how much does the drug cost per item?
NHS England and NHS Clinical Commissioners consultation:

**Items which are not routinely prescribed in primary care: consultation on guidance for CCGs**

- **Healthcare Resource Utilisation** i.e. what NHS resources would be required to implement a change?
- **Annual Spend** i.e. what is the annual spend of the NHS on this item?
  - **Unintended consequences** (see Appendix 2)

We disagree with the proposed criteria as outlined below.

The BMA supports efforts to educate patients about self-care of minor ailments, and encourages the appropriate use of effective medicines that are available from community pharmacies or other retail outlets. We also support the provision of minor ailment schemes within community pharmacies.

We support proper evaluation of the safety and effectiveness of medicines available without prescription, and where there is evidence to show lack of safety or efficacy these substances should be placed on the blacklist of substances unavailable on the NHS. This is in line with the policy outlined for individual prescription-only drugs examined elsewhere in this consultation response.

The right of patients to receive treatment free at the point of delivery (but subject to specific charges as defined in regulation) is a fundamental principle of the NHS, and if this is to be changed it should be done so by legislation on a national basis by those people elected to represent the population and answerable to them for their actions. This is too important a change from established practice to happen on a local basis after local consultation, even if that consultation is nationally co-ordinated.

Any prescribing restrictions must fall within the GMS contract. The relevant paragraph is this:

14.2.2. Subject to clause 14.2.4 and 14.2.5 and to clauses 14.6 to 14.7 a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the Contract by— (a) issuing to that patient a non-electronic prescription form or nonelectronic repeatable prescription completed in accordance with clause 14.2.8; or (b) where clause 14.3 applies, creating and transmitting an electronic prescription.

GPs can advise patients that treatments are available without prescription, but were a GP to refuse to issue an FP10 for treatment that they had recommended they would clearly be in breach of paragraph 14.2.2 and open to complaint and possible financial redress. This would also place GPs in an invidious position with inevitable detrimental effects on GP/patient relationships. We would not support a change from the current wording unless alternative provision for NHS supply, such as through a minor ailment scheme, were provided.

With regard to some of the medicines listed, which are already on the ACBS (Advisory Committee on Borderline Substances) list, it is misleading to imply that these are currently normally available on the NHS, as they are subject to defined criteria for provision. The Advisory Committee on Borderline Substances is the body that should be considering any changes relating to these substances. We would support efforts to ensure that the ACBS medicines were restricted to the intended patient group.

Currently, the Medicines & Healthcare products Regulatory Agency (MHRA) is responsible for market authorisation of these products. Their decisions are made in response to applications.
Items which are not routinely prescribed in primary care: consultation on guidance for CCGs

from the pharmaceutical industry and based on the safety implications of relaxing supply. Their decisions have not taken into account the fact that changing the marketing authorisation of a medicine may in turn limit the availability of that drug on the NHS, with consequential health care implications, and if this had been considered their decisions may have been different. If restrictions to supply of effective medicines are to be determined or influenced by decisions of the MHRA then their operating procedures need to be formally amended to take this into account, and OTC (pharmacy sales) product licences reviewed and rescinded where this proves to be the case.

We are concerned that if prescribing of medicines that are available without prescription is to be restricted, there will be an increase in prescribing of prescription-only medicines that treat the same condition, and that might result in increased prescribing of more expensive antihistamines, or analgesics/NSAIDs with worse safety profiles. This is of particular concern with regard to the increasing numbers of patients with dependence on prescribed analgesics.

For long term conditions, the pack sizes of NSAIDs and paracetamol available without prescription are too small to allow for long term use, and this will be particularly problematic for patients with mobility problems or those living in rural areas.

These proposals will particularly disadvantage vulnerable patients, such as older age groups, patients with disabilities, patients in rural areas, patients with capacity problems including dementia and learning difficulties, people living in poverty or those needing help from carers. The impact of these proposals is therefore likely to include a widening of health inequalities. If arrangements are made for continued provision of medications to vulnerable patients, GPs would be placed in the unacceptable position of having to make value-judgements about the likelihood of patients being able to access the required medication if an FP10 is not provided, and errors of judgement, complaints, and missed treatments would be inevitable.

In summary, our concerns revolve around

- The need for national legislation for such an important change
- The need for protection of vulnerable groups
- The potential widening of health inequalities
- The need for any changes to be within the GMS regulations
- The need for respect for the decisions of the Advisory Committee on Borderline Substances
- The potential for increases in prescribing of less-suitable medicines
- The need for unsafe or ineffective OTC substances to be placed on the blacklist.
- The need for the MHRA to change criteria for licensing drugs.