NHS England Low Value Medicines Consultation Questions With DDA Responses

EQUALITY AND HEALTH INEQUALITIES

Q1: Do you feel there are any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?  
Yes (please tick all that apply)/No  
Age/disability/gender reassignment/race/religion or belief/sex/sexual orientation-marriage and civil partnership/pregnancy and maternity  
Please provide further information on why you think this might be the case.  

- Forced switches made on a patient’s medication regime risks a de-stabilisation of a patient’s disease control. This may be a significant problem for those who are elderly, those who are more easily confused and those who have complex medication regimes (multi-morbidity). This will then have a huge impact on the workload of primary care clinicians see below comment.

Q2. 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/No  
Please provide further information on why you think this might be the case  

- There are four medicines being consulted on that are for pain (co-proxamol, fentanyl, glucosamine and oxycodone and naloxone), as discussed in (equality and Health Inequalities – Full Analysis - Items which should not be routinely prescribed) these medicines are more likely to be taken by patients who have a low income, disabilities, and low educational level. The impact on these patients who have protected characteristics should be more robustly identified and evidenced. The final proposals should also identify evidence based interventions to help support these patients and ensure there is no deterioration of their condition.

- Health care professionals working in a Primary care that is near breaking point because of unprecedented patient demand. The additional workload and increased patient demand created by the prescribing restrictions, dealing with patient concerns/complaints, de-prescribing, issuing alternative treatments and ongoing monitoring could pose a significant risk to GP practices workload, and thus will reduce the availability of GP consultations to practice patients. We estimate this could impact the GP practice with an additional demand of up to 12 additional consultations per patient who had their medication regime changed. There could also be a knock on effect of demand to the wider local healthcare providers.

- We would recommend using some of the medicines cost savings to support GP practices in completing this workload.
GUIDANCE UPDATE AND REVIEW

Q3. 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?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information.

- The guidance will need to be regularly updated to ensure the evidence base on which the recommendations are based does not change, for example any updates in drug safety, changes in cost (both of the restricted medicine and the alternative therapeutic options), and reviews of effectiveness. If compelling new evidence is released on any of the 18 medicines then the guidance will need to be updated in an pro-active and timely manner.

- New item identification should have a longer consultation period than the suggested 4 weeks, some of these decisions are very complex and could have many unintended consequences. A consultation period of 3 months would allow all stakeholders from patient interest groups, industry and those in the healthcare profession to comment and influence recommendations.

- If de-prescribing is the default recommendation for any item identified then the priority criteria should include forecasted impact on healthcare teams workload. Primary care is currently at/near breaking point with patient demand consistently above the available capacity of health care provider organisations. If an item switch is recommended then the work impact must be evidenced with any risks identified and strategies to mitigate those risks.

CCG COMMISSIONING GUIDANCE

Q4. Please select which items you would like to share your views on (please select): Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

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

YES

Do you agree with the proposed recommendations for Dosulepin?

YES

Do you agree with the proposed recommendations for Doxazosin MR?

YES

Do you agree with the proposed recommendations for Fentanyl IM?

YES

Do you agree with the proposed recommendations for glucosamine and chondroitin?

29/9/2017) stated that a review of randomized trials of mostly low quality reveals that chondroitin (alone or in combination with glucosamine) was better than placebo in improving pain in participants with osteoarthritis in short-term studies. The benefit was small to moderate with an 8 point greater improvement in pain (range 0 to 100) and a 2 point greater improvement in Lequesne’s index (range 0 to 24), both likely clinically meaningful. There are no safety concerns with this medication.

Do you agree with the proposed recommendations for herbal treatments?
YES

Do you agree with the proposed recommendations for homeopathy?
YES

Do you agree with the proposed recommendations for lidocaine plasters?
YES

Do you agree with the proposed recommendations for Liothyronine?
YES

Do you agree with the proposed recommendations for Lutein and antioxidants?
YES

Do you agree with the proposed recommendations for Omega-3 Fatty Acid Compounds?
YES

Do you agree with the proposed recommendations for Oxycodone and Naloxone combination product?
YES

Do you agree with the proposed recommendations for Perindopril Arginine?
YES

Do you agree with the proposed recommendations for Rubefacients (excluding topical NSAIDs)?
NO - There is no exceptional circumstances proposal for ongoing prescribing, hence a switch to NSAID gel is highly likely. Therefore the recommendation is very much less likely to save on prescribing costs as intended.

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

Do you agree with the proposed recommendations Travel Vaccines?
YES

Do you agree with the proposed recommendations for Trimipramine?
YES
Q5. 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.

- The proposal to look at the medicines that can otherwise be purchased over the counter and cost the NHS £645million per annum is wide and very far reaching (7% of the current community dispensing costs).

- The NHS constitutional founding principles state that the NHS should provide a comprehensive service ('Principle One') which is free at the point of access. A restriction of medicines available to patients who would receive free medication will break these fundamental NHS principles, effectively breaching ‘Principle 2’ “access to NHS services is based on clinical need not on an individual’s ability to pay”.

- The first category of medicines that would be identified includes 'medicines which are relatively clinically ineffective'. We would recommend that these medicines were first put through a similar consultation process as will be used in the 'low value medicines consultation'. This would ensure there was a reduced risk of un-intended consequences.

- The second category 'medicines which are clinically effective but suitable for self-care and used to treat generally short term/time-limited conditions', that is defined in the NHSE board meeting minutes (July 2017) as a medicine where a medicine has only been prescribed once or twice within a six month period. This recommendation will include a large number of clinical conditions that by their nature go through periods of relapse and remission. If a medicine is needed to control a period of relapse and is restricted to over the counter purchase firstly it may reduce the adherence to treatment plans thereby escalating poor disease control. Secondly it would disjoint patient care, that is the prescriber would have no knowledge on the use of medicines that might indicate/flag a need to clinical review of a patients condition, thereby reducing the quality of care for that patient. Therefore because of the risk of poorer patient's outcomes we do not agree with this NHSE proposal on 'Over the counter medicines'.

- Dispensing practice patients are not allowed in the current regulatory system to purchase from a Dispensing Doctors dispensary any medicine listed in Drug Tariff, unless it is contained in the ‘Black List’. Those rural patients who are not able to access a pharmacy to purchase medicines over the counter could (if the strict recommendations are followed completely by the clinician) receive no-care instead of the intended co-funded self-care, causing a significant inequality for rural patients.

- GP contractors will be in breach of their current NHS contract if they do not provide a prescription for a medicine that is needed for a patient’s treatment. As the contractor is legally obliged, where drugs/medicines are “needed for treatment”, to offer those to the patients on an NHS prescription.

- These recommendations if implemented without professional regulatory body consensus could cause real problems with the ethical difficulties of the prescriber. Prescriber's, not CCGs are responsible for the 'prescribing' decisions they make and must be able to
DDA October 2017: Low Value Medicines NHSE Consultation Official Response

explain and justify them ('prescribing' includes advice). If the prescriber was reported to their professional body currently the healthcare professional could be reprimanded for any decision not to prescribe if the patient has a 'need' for a certain OTC medication.

- A significant change in the NHS healthcare offer (and possibly the constitution) like this would need to be communicated out centrally to reduce the burden of patient engagement communications and patient education on to primary care clinical teams (e.g. GP practice and pharmacy teams).

Q6. 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?
  - **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)

Agree/Neither agree or disagree/Disagree/Unsure. If needed, please provide further information

- Patients who have low incomes rely on the NHS to meet their healthcare needs, if a restriction of over the counter medicines is recommended to CCGs the access to care for this patient group is likely to suffer significantly. The proposed prescribing restrictions would only grow the inequalities in health care accessibility. This is against the NHS founding 'Principles' number two; Access to NHS services is based on clinical need, not an individual's ability to pay.

- Pharmacy medicines have very specific licenses for their use 'over the counter' with quite strict usage guidance for the professional and the patient. This will mean that for some of
the medicines that are restricted from being prescribed will not have a direct licensed alternative available as OTC, which could full-fill an identical treatment plan as the POM ('prescription only medicine' licensed version). For example loperamide 2mg can only be issue as OTC in small pack sizes, has narrower treatment indications, at lower doses (in adults and children), and only for shorter treatment periods (48 hours).

- Over the counter medicines can sometimes be cheaper to the patient from a pharmacy/other outlet, however there are many medicines that the 'Pharmacy' licensed medicines is significantly more costly than the POM version. For example chloramphenicol 1% eye drops cost the NHS on prescription £1.45 (June 2017), while the licensed pharmacy alternative is over £5 to the patient.

Q7. Are there individual products, which are either clinically ineffective or available over the counter which you believe should be prioritised for early review?
Please give detailed reasons for your response.

**NO – We do not agree with these proposals for the reasons list above.**