



# Consultation response

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

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Following our published position statement of 21 July 2017, National Voices has chosen to submit to the above mentioned consultation (hereafter known as the consultation) in the form of a written submission rather than using the online web-form.

### 1. Summary

- 1.1. National Voices is the coalition of charities that stands for people being in control of their health and care. We are sympathetic to the drivers that led to this consultation, and we are also supportive of patients being able to access the most effective medicines. However, National Voices has concerns about the process of this consultation and the potential process of the proposals in chapter 5 which are due to be discussed in a future consultation (hereafter known as the chapter 5 consultation).
- 1.2. In general, we are concerned with the following:
  - 1.2.1. The initial recommendations have not included enough evidence from the people who will be most impacted by these changes
  - 1.2.2. The legality of the what the chapter 5 consultation will be recommending is unclear
  - 1.2.3. Any assessments made in the chapter 5 consultation are at risk of being based on generalisations and criteria that excludes patient impact
  - 1.2.4. The enforceability of any potential guidance has not been communicated

- 1.3. National Voices therefore requests that NHS England increases their patient-based perspective and reviews a much broader depth of evidence with the chapter 5 consultation. We hope to see the consultation working group being able to look more thoroughly and holistically at the impacts of its proposals on patients, primary care prescribers and commissioners.

## Recommendations on the 18 specific treatments in the consultation

### 2. Patient experience based evidence

- 2.1. The consultation documents would suggest that the working group has predominately considered the national cost implications and the national guidance on the treatment's safety and efficacy in making their decisions. While both of these measures are very useful in drawing some initial conclusions, National Voices believes that consulting patient groups with experience of using these treatments could have been beneficial in shaping the initial recommendations.
- 2.2. The realities of treatment efficiency will vary across different people. Patients are able to give a 'real world picture' on what taking this treatment really means and will undoubtedly provide a more holistic picture of its usefulness.
- 2.3. Patients may also be able to assist with the accuracy of recommendations. We have been reliably informed that there is an error in the consultation where it is stated that *"Due to the significant costs associated with Liothyronine and the limited evidence to support its routine prescribing in preference to levothyroxine, the group considered Liothyronine suitable for inclusion in this guidance."* We have been informed that it is extremely rare for Liothyronine to be given in preference to levothyroxine and is instead given in addition to. Seeing as the majority of patients on Liothyronine would also be taking levothyroxine, consulting this group could have prevented this inaccuracy.
- 2.4. National Voices recommends that the proposed chapter 5 consultation actively includes more evidence from patients who have experience of being prescribed these treatments.

### 3. Prescriber rationale evidence

- 3.1. In addition to not reviewing patient experience evidence, National Voices notes that the working group did not appear to review the reasons behind why a primary care professional would choose to prescribe these items for their patients.
- 3.2. We are under the impression that many GPs and professionals who have been prescribing treatments like Dosulepin would have decided that in their professional opinion any potential safety risks are mitigated by the very specific circumstance that is presented by an individual patient. Additionally, while prolonged release Doxazosin may be six times the cost of immediate release Doxazosin, practitioners may have experience or anecdotal evidence that the prolonged release drug has other benefits or is easier for more vulnerable patients to take.
- 3.3. We also think it is worth noting that there appears to be significant regional differences in the amount of money spent on some of the 18 prescribed treatments when broken down to a CCG level. Some of the treatments listed, such as Oxycodone & Naloxone, Homeopathic treatments and Lutein & Antioxidants, have a disproportionate amount of spend in only a handful of CCGs. This could indicate that only a small number of GPs have a different rationale for prescribing, and that targeted education may be more effective in achieving the consultation's aims.
- 3.4. National Voices recommends that the proposed Chapter 5 consultation looks at prescriber rationale and motivations from the beginning in order to make sure that all aspects of the debate are openly explored.

### 4. Secondary care evidence

- 4.1. National Voices recognises that this consultation only seeks to look at primary care prescriptions, however many of the patients using these treatments will also be seen by health professionals in a secondary care setting. They may therefore start requesting these treatments from alternative secondary care sources if their primary prescriber refuses to.
- 4.2. While the working group did discuss in Appendix 2 the potential impact that these reforms could have on secondary care and suggested that

“this will need monitoring”, there is no evidence that secondary care providers have been consulted. It is also not clear from the consultation documents how this impact is expected to be monitored.

- 4.3. National Voices recommends that as the working group moves towards the chapter 5 consultation, more secondary care providers are consulted as key stakeholders who can provide a more holistic view of the potential impact that these decisions could cause.

## 5. Enforceability and communication of the consultation findings

- 5.1. The consultation indicates that following this process, NHS England hopes to produce “commissioning guidance” that will ensure consistency and address unwarranted variation. It is also indicated that while it is hoped that this will lead to a more equitable process for making decisions, CCGs will need to take individual decisions on implementation locally. National Voices is therefore concerned that any obligations produced by the guidance are enforced safely and carefully communicated to CCGs, primary care providers and patients.
- 5.2. The terminology of ‘guidance’ could indicate that the contents are discretionary and there is scope for some situations to be considered as exceptions. Both CCGs and primary care providers will need to be informed on what they should do if they believe that a certain patient has individual requirements that justify continued access to a treatment listed here.
- 5.3. If however the guidance is obligatory and it is the intention that no exceptions should be made then the enforcement of this must be done safely. In addition to safe communication, we would hope that there would be a level of monitoring to ensure those patients that can no longer access these treatments are not in danger
- 5.4. Patients should also be communicated with about both the enforceability of the guidance and the motivations behind it. We know from our members that many older people can feel they’re having treatments removed because they no longer “deserve” them. Therefore if a patient is having a drug taken away, it is important that they know the reasons why, and are given the opportunity to review and discuss an alternative care plan with their prescribers.

# Recommendations on Items that are prescribed in primary care and are available over the counter

## 6. Legality and the NHS constitution

- 6.1. National Voices is supportive of general self-care principles and believes that patients should be supported in effective self-care techniques. We are therefore sympathetic to the general aim of chapter 5. However, National Voices is significantly concerned that the impact of these proposals is tantamount to a breach of the NHS constitution.
- 6.2. The NHS constitution states that "*NHS services are free of charge, except in limited circumstances sanctioned by Parliament*". Indeed the introduction of prescription charges and decisions on who is eligible for free prescriptions has in the past been taken by parliament. The consultation does not state how much of the approximate £645million spent on chapter 5 items was provided to patients who were eligible for free prescriptions, however the Government's own figures report that 90% of overall prescription items are dispensed without charge. National Voices is therefore concerned that these chapter 5 proposals are effectively bringing forward a new charge on an NHS service which, until now, 90% of people have been receiving for free. We therefore believe that without parliamentary approval, this recommendation is in breach of the NHS constitution.
- 6.3. The consultation's equalities and health inequalities analysis states that the chapter 5 proposals "may impact those who receive free prescriptions" and that "this will therefore be considered further as part of the full impact assessment for this element of the project". National Voices strongly welcomes further, robust health inequality analysis of this proposal – especially on those who currently receive free prescriptions.
- 6.4. We also hope that any impact assessment will be combined with clear legal advice on constitutional compatibility. National Voices is certain that any future consultation on this matter must show that NHS England's proposals are not generating a fee for an otherwise free NHS service.

## 7. Categories of product and assessment criteria

- 7.1. National Voices appreciates that because a systematic process of identifying which treatments could be considered as a chapter 5 item is needed, there also needs to be clear assessment criteria and categories in order to make recommendations. However, the first of the categories is “further medicines additional to those identified in chapter 4 above which are relatively clinically ineffective”. We would be very grateful if NHS England could confirm why there are medicines which fit the criteria of chapter 4 that are not being considered now, in detail, in this current consultation.
- 7.2. Further to this, we have concerns that the working groups assessment criteria do not fully look at the impact that these proposals could have on patient groups. As stated in point 2 above, because there has also not been any patient experience-based evidence included yet, the working group is at risk of missing key practical impacts of their decisions.
- 7.3. National Voices recommends that the assessment criteria be added to in order to include more patient focused impact considerations. In particular the criteria should consider what the financial implications for the patient are, not just the financial implications on the NHS. This would include looking at matters like medicine unit cost, potential for market fluctuations, frequency of need, likelihood of being on other costly medications and whether there are restrictions on the quantity of the treatment that can be purchased over the counter. For example, those who need paracetamol are restricted to purchasing 32 tablets at a time. Those taking a maximum dosage of 8 tablets a day would therefore be required to purchase paracetamol every 4 days.
- 7.4. Another patient focused criterion not currently included is the likelihood and effects of non-adherence. Not only could this have an impact on the individual but also on wider public health. We know there are already people, especially those on very low incomes, who choose to buy food or heat their homes rather than buying their prescription. We also know of patients who choose to take a lower dose of the drugs they have been given in order to make their prescription last longer, even if it then has a lesser effect. We believe the working group should consider whether not taking the drugs could result in the patients’ deteriorating or developing a more severe secondary complication that results in requiring further primary or secondary care.

- 7.5. All of the unintended consequences listed in Appendix 2 of the consultation document look at consequences of the proposals on prescribers, pharmacists and the NHS. We would hope that the working group would also seek to look at potential unintended consequences to patients and their families too.

## 8. Assessment process

- 8.1. The consultation document states that *“having identified products which are considered to fall into the [three] categories, it is then proposed that detailed consideration is given to each product using the criteria as outlined... Using these criteria, the... working group will consider items available for purchase over the counter in the coming months and where appropriate will develop detailed guidance for further consultation.”* We are pleased to see that the working group intends to review each over the counter product individually. However, by the consultation’s own admission, this could be over 3,000 individual treatments. We are therefore concerned that if this thorough process is deemed to be impossible, the consultation will seek to group large amounts of products together and make sweeping recommendations.
- 8.2. National Voices is concerned that any attempt to group over the counter treatments in artificial ways immediately results in overarching generalisations on the patients who are using them. When recommendations and policies are made on generalisations, this often creates an onus on individuals to either prove they have a clinical need or to prove they are an exception to a generalist rule.
- 8.3. We would also be wary of any attempts to assess the items by grouping together cohorts of patients. Not only does this go against the fundamental principles of person-centred care, but it is far more likely to promote stereotypical generalisations and/or ignore individual complexities. It would also exacerbate the likelihood of certain individuals needing to prove they are an exception to general rules.

## Contact

National Voices thanks NHS England for the opportunity to submit our thoughts on this consultation. We would like to offer our continued engagement on this issue and hope to be able to work together to ensure that any guidance fulfils the principles of high quality coordinated care



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Please contact National Voices' Policy and Public Affairs lead, Hannah Chalmers, if any further clarification is required on the contents of this consultation. Her email is [hannah.chalmers@nationalvoices.org.uk](mailto:hannah.chalmers@nationalvoices.org.uk),