Items which should not be routinely prescribed in primary care: Consultation Report of Findings

NHS England

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Items which should not be routinely prescribed in primary care: Consultation Report of Findings

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2 Background

2.1 The issue to tackle

NHS England has partnered with NHS Clinical Commissioners (NHSCC) to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing resources effectively and deliver best patient outcomes from the medicines that their local population uses. CCGs asked for a nationally coordinated approach to the development of commissioning guidance in this area to ensure consistency and address unwarranted variation. The aim is that this will lead to a more equitable process for making decisions, addressing unwarranted variation, and provide clear guidance on medicines. CCGs, however, will need to take individual decisions on implementation locally.

Last year 1.1 billion prescription items were dispensed in primary care at a cost of £9.2billion. This cost coupled with finite resources means it is important the NHS achieves the greatest value from the money that it spends. We know that across England there is significant variation in what is being prescribed and to whom. Often patients are receiving medicines which have been proven to be relatively ineffective or in some cases dangerous, for which there are other more effective, safer and/or cheaper alternatives.

The 'Items which should not routinely be prescribed in primary care – a consultation on guidance for CCGs' - ran between 21 July and 21 October 2017. Responses to our proposals were received through the online survey, webinars, public events and correspondence in the form of letters and emails.

NHS England and NHSCC, alongside their joint clinical working group, have reviewed the consultation findings contained in this report and developed finalised commissioning guidance for approval by the NHS England Board. The guidance will then be published with the expectation that CCGs should 'have regard to' it in accordance with the Health and Social Care Act 2012.

The NHS England and NHSCC led clinical working group developed guidelines regarding a list of 18 products which they considered to be ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS.

The 18 items were categorised under three headings:

- *Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns:* Co-proxamol, Omega-3 fatty acid compounds, Lidocaine Plasters, Rubefacients, Dosulepin, Glucosamine and Chondroitin combination product, Lutein and Antioxidants combination product, Oxycodone and Naloxone combination product, Homeopathy, Herbal Medicines

- *Products which are clinically effective but where more cost-effective products are available (this includes products that have been subject to excessive price inflation):* Liothyronine, Prolonged-release Doxazosin, Perindopril Arginine, Immediate-release Fentanyl, Once Daily Tadalafil, Trimipramine, Paracetamol and Tramadol combination product

- *Products which are clinically effective but deemed a low priority for NHS funding:*

Travel Vaccines (Public Health England will be undertaking policy work on this).

The group also sought views generally on the potential restriction on prescription of over the counter medicines used for generally minor and/or self-limiting conditions. These included:

- Products that can be purchased over the counter, and sometimes at a lower cost than would be incurred by the NHS
- Products that treat a condition that is considered to be self-limiting and so does not need treatment as it will heal or be cured of its own accord, and/or
- Products that treat a condition which lends itself to self-care, i.e. that the person suffering does not normally need to seek medical care and/or treatment for the condition.

NHS England commissioned NHS Midlands and Lancashire Commissioning Support Unit (MLCSU) to collate and analyse all of the feedback from this consultation and produce this report which has been considered in full by NHS England.

3 Engagement methodology and feedback

Engagement was structured around the following channels and feedback mechanisms:

Breakdown of responses according to feedback method		
Feedback methods	**No. responses from feedback method**	**Action taken**
Online survey (comprising 75 closed questions and 26 open questions)	5,544	Closed questions are tabulated by respondent type. Open questions are coded, key quotes identified and tabulated by respondent type.
Patient and public correspondence (email and letters)	95	Each correspondence was read and coded against the online survey coding frame. The data was then coded and a summary report was written.
Organisational correspondence (email, letters and formal correspondence)	80	Each correspondence was read and summarized.
Letters from MPs including one parliamentary briefing	20	Each correspondence was read and summarized.
Webinars (professional and industry)	5	Summaries have been written for each of the products mentioned in the discussion.
Webinars (patient and public)	3	Summaries have been written for each of the products mentioned in the discussion.
Engagement events	2	Summaries have been written for each of the products mentioned in the discussion.
Events and meetings (professional and industry)	3	Summaries have been written for each of the products mentioned in the discussion.

Analysing feedback received

The consultation survey included a combination of ‘open text’ questions (e.g. If needed, please provide further information) where respondents could share their views and opinions as well closed questions where respondents ‘ticked’ a response to a set of preset responses (e.g. ‘To what extent to do you agree with X’ and the answers are: agree, disagree, neither or unsure). The closed questions were tabulated and responses shown by respondent type.

The ‘open text’ questions were handled differently. A random sample of around 200 responses for each ‘open text’ question was initially read in order to create and list key themes (codes) raised by respondents. This was undertaken for every question. Some codes were replicable across more than one response (e.g. ‘NHS funds should not be used to pay for this’) whilst others were specific to a particular product or question. This means that every comment was coded because the list of themes/codes was not predetermined but instead emerged dynamically from the responses received.

The coding frame was then used to read, code and analyse every single response received from patients and the public. **This has ensured that all responses can be considered by NHS England and be compared and analysed together**. Supporting evidence, reports, academic papers etc. which were submitted by organisations are being reviewed by NHS England separately as appropriate.

Responses from specific organisations were read and summarised. These summaries have been referred to in this report.

3.1 Survey respondent types and patient demographics

Overall 5,544 individuals completed the survey, with the majority (69%) of responses coming from patients and members of the public. However responses were also received from other respondent types, including; Clinicians, Clinical Commissioning Groups, NHS Provider Organisations, Professional Representative Bodies and Industry.

Focussing on the patients specifically, the majority were; women, heterosexual, aged between 30 and 79 and of British ethnicity.

Respondent types and patient demographics			
Respondent type (total)	**No.**	**Gender**	**No.**
Patient	**2,638**	Female	2,041
Member of the public	1,200	Male	496
Clinician	775	Non binary	9
Family member	209	Trans	6
Clinical Commissioning Group	131	Intersex	1
Friend or carer of patient	99	Prefer not to say	64
Patient representative organisation	85	*Total*	*2,638*
NHS provider organisation	59		
Professional representative body	51	**Sexual orientation**	**No.**
Voluntary organisation or charity	45	Heterosexual	2,095
Other healthcare organisation	44	Bisexual	48
Industry	29	Gay	28
Other NHS organisation	25	Lesbian	21
Regulator	3	Prefer not to say	356
Other	123	*Total*	*2,638*
Total	*5,516*		
Age	**No.**		
Under 18	3	60 – 69	599
19 – 29	74	70 – 79	218
30 – 39	347	80+	33
40 – 49	581	Prefer not to say	33
50 – 59	702	*Total*	*2,638*
Disability	**No.**		
Yes	847	Prefer not to say	230
No	1,529	*Total*	*2,638*
Religion/beliefs	**No.**		
Christian	1,068	Jewish	19
No religion	916	Hindu	10
Prefer not to say	270	Sikh	6
Atheist	143	Any other religion	87
Buddhist	30	*Total*	*2,638*
Muslim	22		
Ethnicity	**No.**		
White: Welsh/ English/ Scottish/ Northern Irish/ British	2,181	Mixed: White and Asian	7
Other White background	217	Black or Black British: Black - Caribbean	6
White: Irish	41	Asian/Asian British: Bangladeshi	5
Other ethnic background: Any other ethnic group	33	Black or Black British: Black - African	5

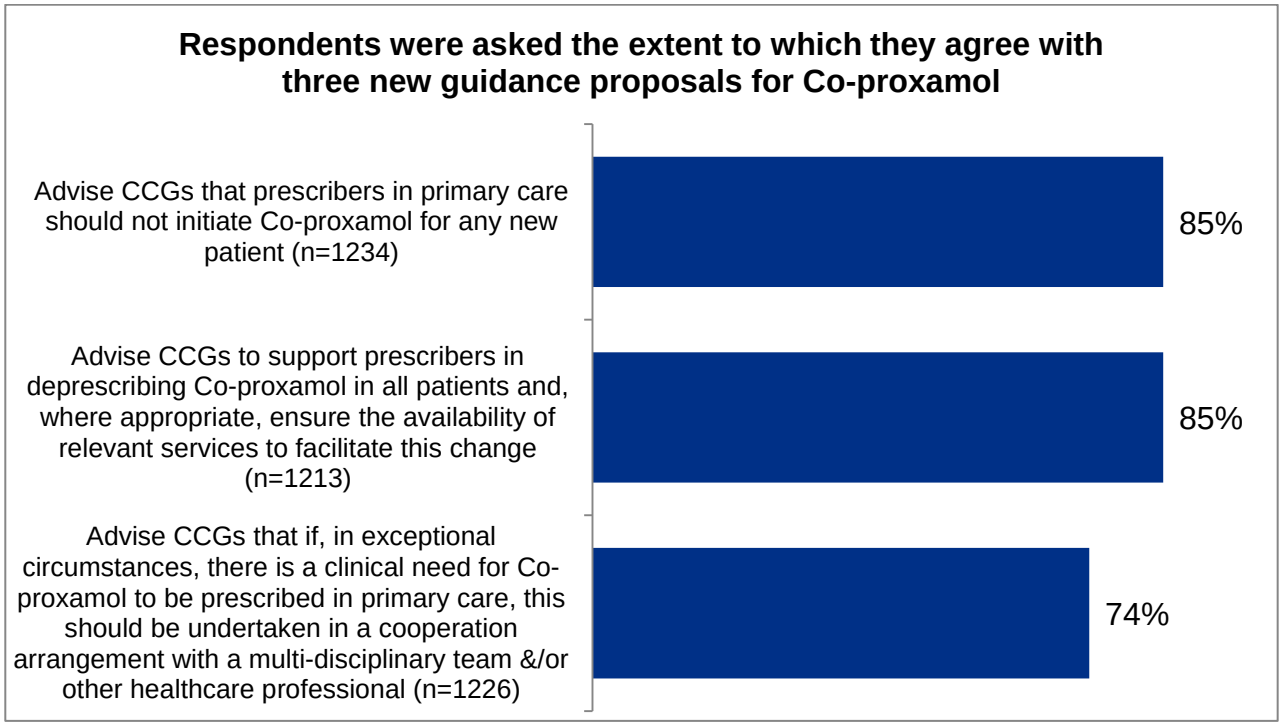
Asian/Asian British: Indian	28	Mixed: White and Black African	4
Any other mixed background	19	Black or Black British: Any other Black background	2
Asian/Asian British: Pakistani	10	White: Gypsy or Irish Traveller	1
Mixed: White and Black Caribbean	10	Other ethnic background: Chinese	0
Asian/Asian British: Any other Asian background	7	*Total*	*2,638*

4 Responses by item

4.1 Co-proxamol

Co-proxamol is a painkiller that was previously licensed in the UK until being fully withdrawn from the market in 2007 due to safety concerns. All use in the UK is now on an unlicensed basis. The inclusion of Co-proxamol within this consultation is due to the significant safety concerns associated with it (fatal overdoses).

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Some patients state that Co-proxamol is an effective treatment that has provided patients with long-term relief and ask NHS England to consider the additional demand that will be placed onto healthcare professionals if it is removed. It is more likely to be used in older patients who have been using it for a long period of time and are, therefore, most likely to be affected by this proposal.
"Co-proxamol used to be the best painkiller I had. It was as effective as codeine without making me drowsy. It was the only painkiller I could function on."

However, some patients (10) suggested that Co-proxamol should be blacklisted because of safety concerns.

Members of the public and family members

This cohort voices concern about the safety of Co-proxamol and supports the motion of blacklisting the treatment. Additionally, some state that there are alternative treatments available with similar efficacy.

"Blacklist Co-proxamol – should not be available under any circumstance."

CCGs

Responses from this group generally support the proposal. They state the guidance around Co-proxamol should be strengthened and the treatment blacklisted. They express safety concerns with the use of Co-proxamol and state there are alternatives available with similar efficacy.

"CCGs and clinicians do not need any further 'guidance' or 'recommendations' on prescribing. We need a change in NHS regulations to prevent prescribing. Medicines Optimisation teams have worked to review and stop Co-proxamol prescribing since the original safety warnings, but we cannot eliminate prescribing due to small numbers of patients exerting pressure on clinicians. Bury has an excellent record in the implementation of cost-effective prescribing guidance, but we still struggle to eliminate inappropriate prescribing across all practices and clinicians."

Clinicians

Clinicians generally also support the proposal, expressing safety concerns and also stating that it is an expensive treatment. Using stronger wording in the guidance and blacklisting the treatment are also prominent themes amongst this cohort. A small sub-set of this group states Co-proxamol is an effective treatment, and there may be scope to prescribe it in exceptional circumstances.

"Previously, I was a PCT chief pharmacist, and during my 10 years in post we managed to work with our GPs to stop prescribing Co-proxamol for all but one patient in our PCT area. I am surprised that we are still spending over £9 million on Co-proxamol. It has no place in therapy, and presents significant safety concerns. While I understand that it can be difficult to convince some patients of the need to stop using Co-proxamol, there is no excuse for not trying. I would consider raising performance concerns about any prescriber who has initiated Co-proxamol since it was withdrawn in 2007."

Patient representative organisations, voluntary organisations and charities

The key themes to emerge amongst this cohort are the requirement to consider the impact on healthcare professionals as a result of this treatment not being available; multi-disciplinary team involvement in the prescription of this treatment not being a good use of resources; safety concerns around Co-proxamol's use; and the requirement for clearer definitions in the guidance. There is also a need to consider the impact this proposal will have on those for whom Co-proxamol has been effective in providing long-term relief.

Other NHS organisations, provider organisations and professional bodies

Comments from other organisational bodies convey their support for the proposal, expressing concern around safety of this treatment and a need for clearer guidance to avoid any misunderstanding and inappropriate patient expectations that it is still available in exceptional circumstances.

This group also suggests an additional reason for not prescribing it at all is because there are a number of safer, effective alternatives.

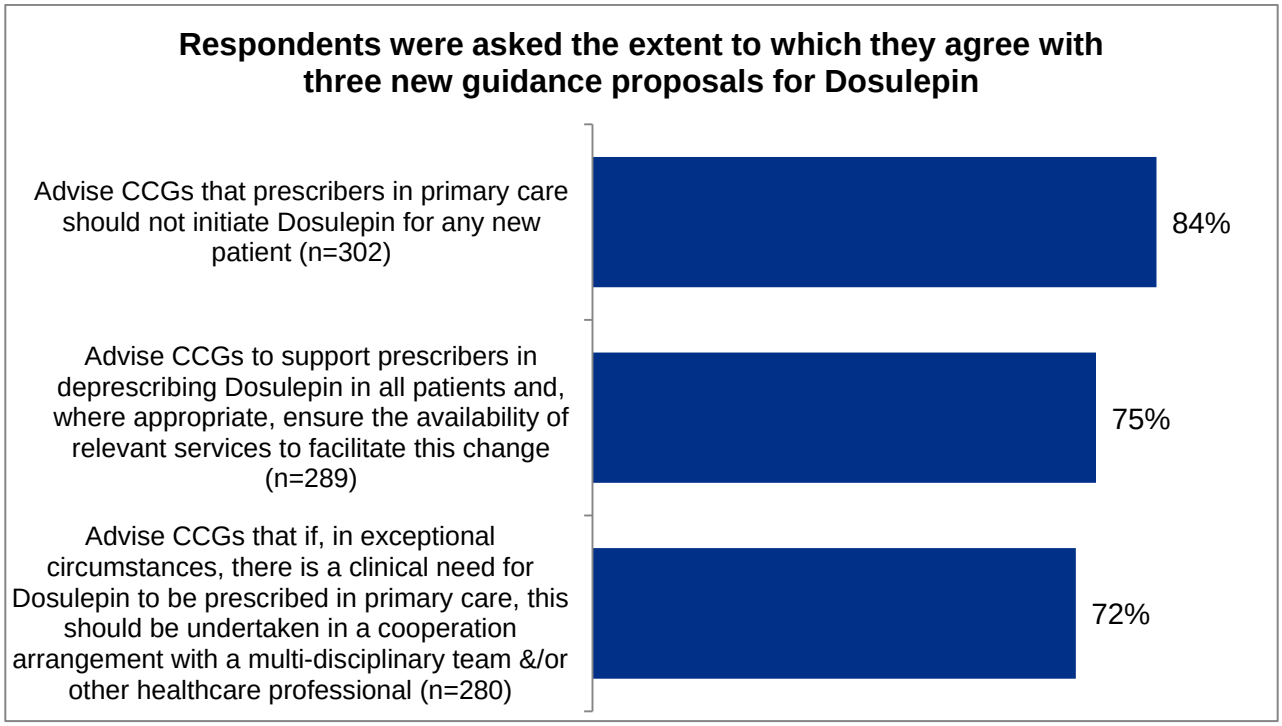
NICE agrees with all of the proposed guidance in relation to Co-proxamol.

The Royal Pharmaceutical Society also agrees with the proposal, citing safety concerns and the availability of alternatives. The British Medical Association disagree that CCGs should be advised 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. The BMA think that due to its toxicity, co-proxamol should either be placed on the blacklist of drugs unavailable on the NHS or be restricted to prescription by a specialist.

4.2 Dosulepin

Dosulepin is an anti-depressant. NICE includes Dosulepin in its 'do not do' recommendation because it has a high chance of causing heart problems, is toxic in overdose and there are other anti-depressants available which are safer to use.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Themes raised by patients in their comments were that: this is an effective treatment; and alternatives don't suit all patients, therefore Dosulepin is the only suitable medication for them.

"If I cannot be prescribed Dosulepin, I will not be able to function. I will have to give up work and social activities. I will be in constant pain."

Members of public and family members

The majority of members of the public agree with the proposals mainly because they feel that if there are safety risks associated with taking Dosulepin, it shouldn't be prescribed or available at all. They also feel that there should be clear guidance and explanation

about what constitutes an exceptional circumstance.

"Has a 'do not use' warning, significant risks of use, and there are numerous other medications which could be prescribed instead. Risks outweigh benefits."

CCGs

CCGs believe prescribing of Dosulepin should stop and it should be blacklisted. However, one of the top five themes from this group is that patients who currently use the Dosulepin should be able to continue to use it.

"New patients should not be initiated, however it is felt that where patients are currently prescribed the treatment and are stable – then they should remain on treatment, as there may be implications which cost more to the system, and could result in poor patient outcomes/patient experience by trying to stop treatment."

Clinicians

Clinicians make a number of comments in agreement with the proposals. Some state that as this is the only medication that works for some patients, those who currently use it should be able to continue to do so.

"This drug has a very small role and is useful in a tiny number of patients."

Patient representative organisations, voluntary organisations and charities

The majority of this group agrees with the recommendations for new patients. However, just a quarter agree with the recommendations for deprescribing Dosulepin for all patients, with others stating that for some patients it is the only option that works.

Other NHS organisations, provider organisations and professional bodies

Other organisations think that the prescribing of Dosulepin should be reviewed and deprescribed where appropriate. Where this is not deemed possible there should be a coordinated approach between primary and secondary care. Some organisations support this proposal stating safety concerns about the use of Dosulepin.

The Royal Pharmaceutical Society says that Dosulepin should continue to be prescribed for the small number of patients, mainly elderly, who benefit from it. They may not be able to tolerate switching to an alternative which could lead to increase costs to the NHS. Phasing out Dosulepin over time may be a more realistic approach.

"Patients already on this medicine have been stabilised … for many years. We are going to take them into an unknown state. Where appropriate, the clinicians should be able to prescribe this [if] in their opinion [it] would be the most suitable for their patients." (NHS provider organisation)

Industry

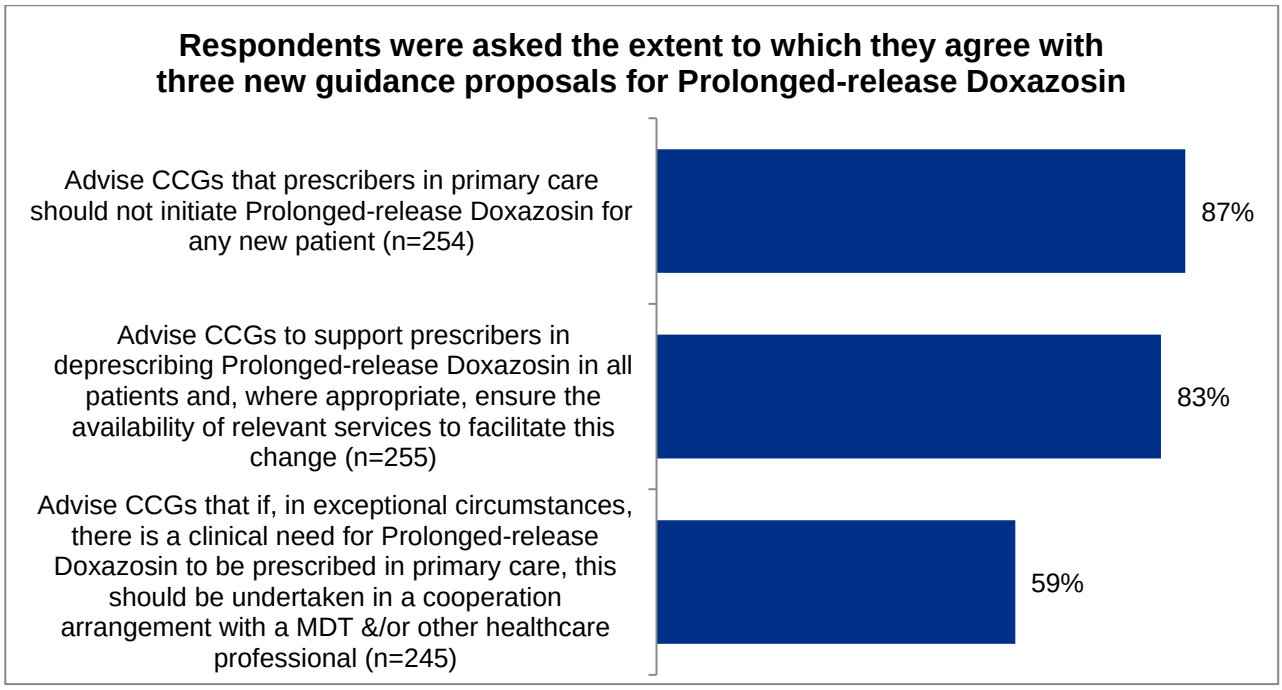
The one response from industry neither agrees nor disagrees.

"Agree that there may be suitable alternatives however for those patients who are currently on treatment; to be continued with support. Agree for use in new patients in exceptional circumstances. However exceptional circumstances should be pre-defined in NHS guidelines."

4.3 Prolonged-release Doxazosin

Prolonged-release Doxazosin is a drug that can be used to treat high blood pressure/hypertension (in men and women) or prostate problems in men (benign prostatic hyperplasia). There are two oral forms of the medication (immediate-release and prolonged-release) and both are taken once daily. The inclusion of Prolonged-release Doxazosin within this consultation is due to the fact that it is approximately six times the cost of Immediate-release Doxazosin, which is also more readily available.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

This cohort is divided in support for these recommendations, some quoting the side-effect profile of Immediate-release Doxazosin as the main contributing factor.

"Some patients have resistant-controlled high blood pressure, whichever medication they are prescribed. To remove this tablet and put them on the standard release one could totally upset their blood pressure long-term."

Members of the public and family members

Some respondents agree with the proposal however, some state that the treatment should be prescribed with input from primary and secondary care.

"This item is likely to be on hospital prescribing formularies and therefore there must be a joined-up approach between primary and secondary care."

CCGs

Most comments from CCGs state that they feel this product should be blacklisted. This group would welcome a robust definition of exceptional circumstances as well as clearer guidance and education material from NHS England to support the implementation of these recommendations, including the role of the multidisciplinary team.

"No clinical need for Prolonged-release Doxazosin, however significant use so will be difficult to implement. Some clear guidance regarding 'no clinical rationale for use' will be essential to get GPs to agree."

Clinicians

Like CCGs, clinicians agree that this treatment should be removed or blacklisted. This group would also welcome a robust definition of exceptional circumstances as well as clearer guidance and education material from NHS England to support the implementation of these recommendations, including the role of the multidisciplinary team.

"Immediate release is once daily, no value in MR therefore should be unavailable for prescribing and blacklisted."

Patient representative organisations, voluntary organisations and charities

One respondent from this cohort observes that Prolonged-release Doxazosin and Immediate-release Doxazosin are both taken once daily – so there is no need for Prolonged-release Doxazosin.

Other NHS organisations, provider organisations and professional bodies

The majority of organisations are in support of the proposals. Like CCGs and clinicians, they would welcome further guidance on the proposal in regards to implementation. A small number of these bodies are against the proposal or just an aspect of it.

"Evidence from practice and dealing with patients would suggest that many patients cannot tolerate Immediate-release Doxazosin."

NICE agrees with all three recommendations, and also notes that when exercising their judgement, health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in NICE guidance is at the discretion of health professionals and their individual patients and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

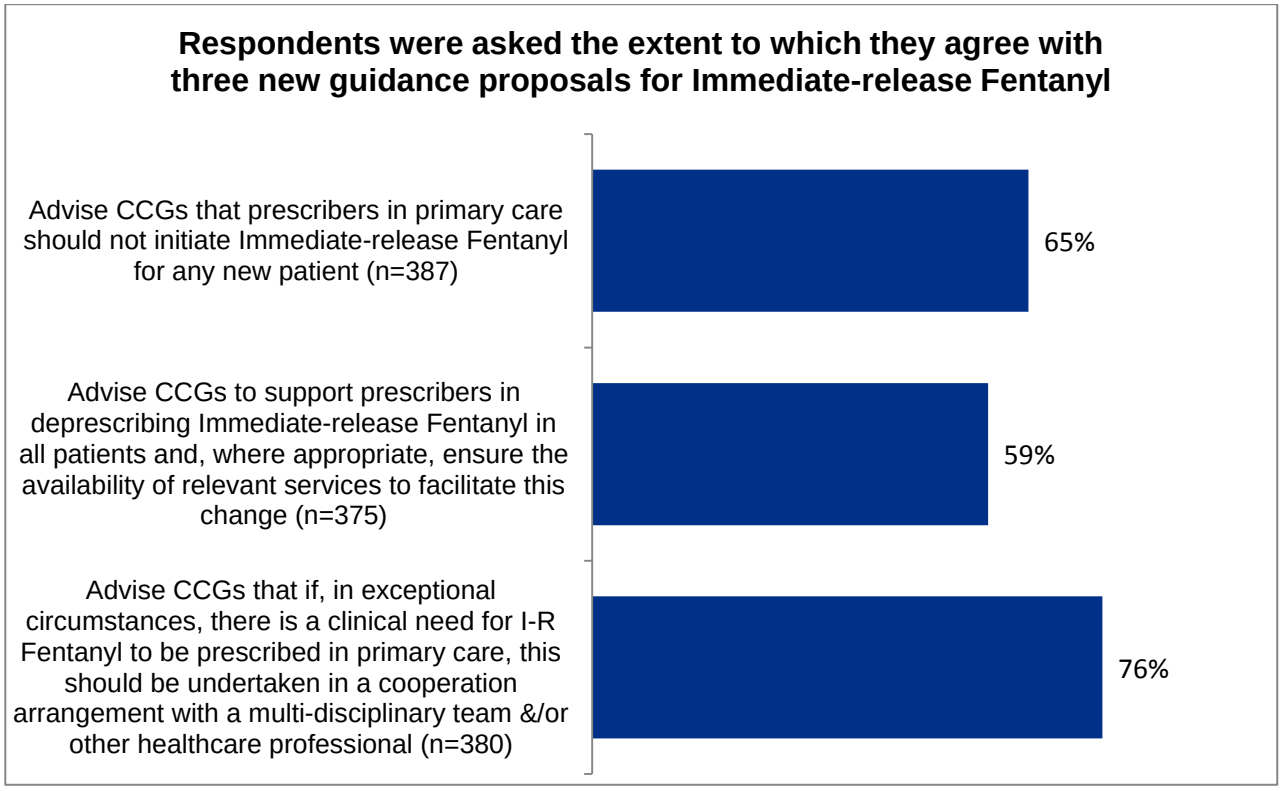
Middlesex Pharmaceutical Group of Local Pharmaceutical Committees mildly disagrees with this proposal. However, they say that CCGs should be advised that if, in exceptional

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 professional.

4.4 Immediate-release Fentanyl

Immediate-release Fentanyl is a painkiller, similar to Morphine. It is available in various forms, such as tablets, lozenges, film and nasal spray, and is licensed for the treatment of breakthrough pain in adults with cancer who are already receiving at least 60mg oral morphine daily or equivalent. NICE CG140 Opioids in Palliative Care states 'Do not offer fast-acting Fentanyl as first-line rescue medication'. Consensus of the working group is that the small number of people this would apply to does not justify current prescribing volumes. Due to the recommendations from NICE and Immediate-release Fentanyl being only licensed for use in cancer, the group considers it suitable for inclusion in the proposed guidance. This recommendation does not apply to longer sustained release versions of Fentanyl which come in patch form.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients highlight that if this product were removed there would have to be a plan in place for those needing to be managed off it because it is the only effective treatment for some patients.

"Immediate pain relief, especially for cancer suffers, is important. If it is being routinely prescribed, than we should assume that GPs are doing this for a good reason. No-one should have to endure unnecessary pain."

Members of the public and family members

Similarly to patients, this cohort also feels Immediate-release Fentanyl is an effective treatment, and therefore a plan must be in place for those who must be managed off it. Additionally, respondents feel that the prescribing decision should remain with healthcare professionals, giving them the option to also prescribe alternative forms of the treatment where required.

CCGs

CCGs largely support the recommendations but caveat there may be exceptional circumstances when it is appropriate to prescribe in primary care. They argue the use of this treatment in palliative care is justified. CCGs highlight safety concerns with the misuse of this treatment, therefore it should be restricted for those who show a genuine clinical need and this is where further guidance and education from NHS England is required to ensure it is implemented effectively.

Clinicians

Clinicians state the use of this treatment in palliative care is justified as they feel it is an effective treatment. They say that therefore the impact on palliative care patients must be considered when considering this proposal.

Regarding deprescribing Immediate-release Fentanyl, some clinicians feel they may need to consult with specialists before attempting to withdraw this medication. However, some feel the prescription of this treatment in palliative care should continue.

Patient representative organisations or voluntary organisations and charities

The key themes to emerge from this cohort are that it is an effective treatment that should be prescribed to whoever requires it regardless of whether it's primary, secondary or palliative care; and that it is beneficial to have numerous treatment options available rather than relying on a select few.

Patient representative organisations also stress the potential impact on patients if this treatment is removed, with some feeling this guidance has come about due to the cost of the treatment. The Patients Association feels this treatment should only be prescribed following the input of multi-disciplinary teams or a specialist. Marie Curie adds that patients with conditions which lead to poor renal function have been overlooked. Unlike some other opioids, Fentanyl is expelled from the body through the liver rather than the kidneys, making it an important pain control drug for those with poor renal function.

Other NHS organisations, provider organisations and professional bodies

This cohort considers that although this treatment is effective, its use should be restricted to those with a major clinical need, such as palliative care and cancer patients. Therefore, this group requires clear guidance and education from NHS England to ensure the proposed guidance is effectively implemented.

NICE agrees with the proposed guidance for this treatment and recommends Immediate-release Morphine for breakthrough pain, which is also used and cited by the Royal Pharmaceutical Society. The British Medical Association disagree and say that Immediate-release Fentanyl is an extremely effective analgesic whose 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. Furthermore, the availability of immediate analgesia may avoid unnecessary hospital admission. They 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

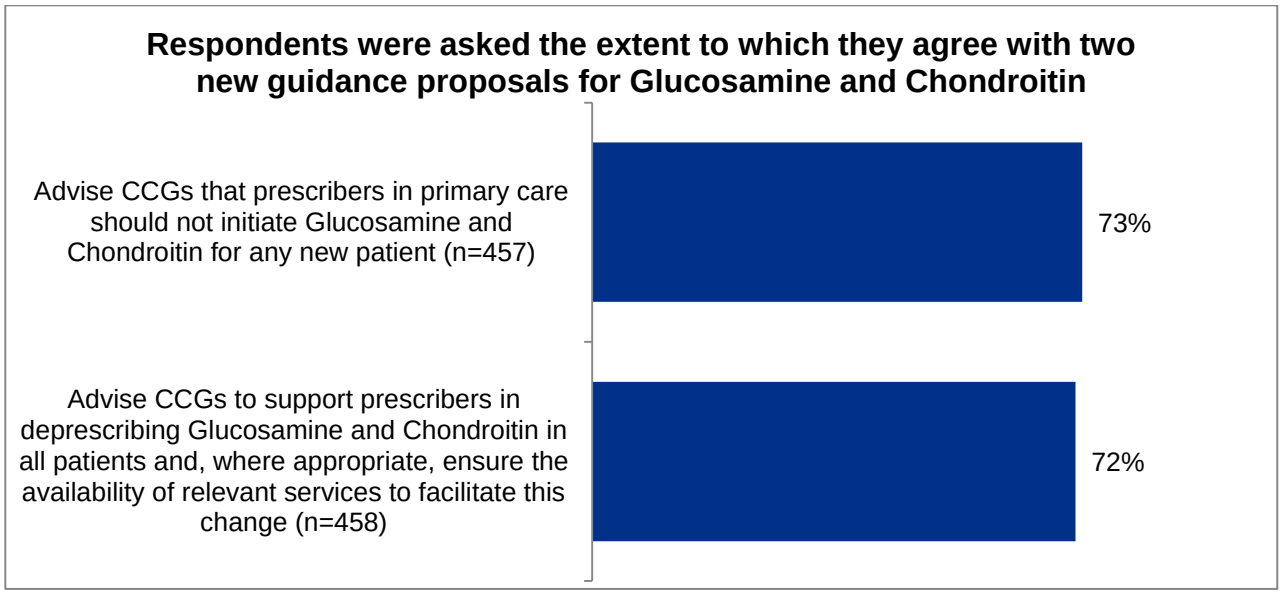
Industry

Some industry representatives feel restricting primary care access to this drug would have unintended consequences that will have a detrimental impact on outcomes and experience of care, particularly for terminal cancer patients being cared for at home, in the community and hospice units. Teva disagrees with the recommendations, citing the impact on patients as they are taken off this treatment and the potential commercial implications if manufacturers of alternative products increase their costs.

4.5 Glucosamine and Chondroitin

Glucosamine and Chondroitin are dietary supplements used to improve pain associated with osteoarthritis; a condition that causes joints to become painful and stiff. Osteoarthritis is the most common type of arthritis in the UK. Glucosamine and Chondroitin can be bought over the counter from pharmacies, supermarkets and health food stores. Their inclusion in this consultation is due to the lack of evidence to show they are effective in the management of osteoarthritis.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients feel that Glucosamine and Chondroitin are effective treatments. However, some state there is a lack of evidence that proves their effectiveness. Points are also raised about the availability of these treatments over the counter and how they should not be funded by the NHS but by the patient if it is their choice of treatment or a lifestyle choice.

"I meet people who swear by these. To remove [them] would be psychologically damaging if nothing else."

Members of public and family members

Like patients, this respondent group point out that Glucosamine and Chondroitin are effective treatments. They also note that these treatments are available over the counter and some responses demonstrate support for them not being prescribed.

CCGs

Common themes from CCGs are a lack of evidence for the effectiveness of these treatments and the view that they should not be prescribed. Some CCGs also highlight that this treatment is available over the counter and should be funded by the patient not the NHS as it is a lifestyle choice.

"The same argument is still valid that in order for something to be valid for a prescription there needs to be an evidence base to back it up."

Clinicians

Like CCGs, some clinicians state that Glucosamine and Chondroitin should not be

prescribed. This group also highlights the availability of these treatments over the counter and that they should be patient-funded if they choose to use them. Some clinicians also mention the lack of evidence for their effectiveness.

"Patients can be directed to purchase these items over the counter."

Patient representative organisations, voluntary organisations and charities

Most of this cohort agrees with the proposal, citing the availability of the treatments over the counter; lack of evidence for their effectiveness; and belief that the treatments, as a lifestyle choice, should be funded by the patient not the NHS. One organisation argues that the treatments are effective.

Other NHS organisations, provider organisations and professional bodies

This group raises points about the availability of the treatments over the counter; lack of evidence for their effectiveness; and belief that the treatments, as a lifestyle choice, should be funded by the patient not the NHS. NICE and the Royal Pharmaceutical Society are some of the organisations that support the recommendations. A small group of organisations say it is an effective treatment.

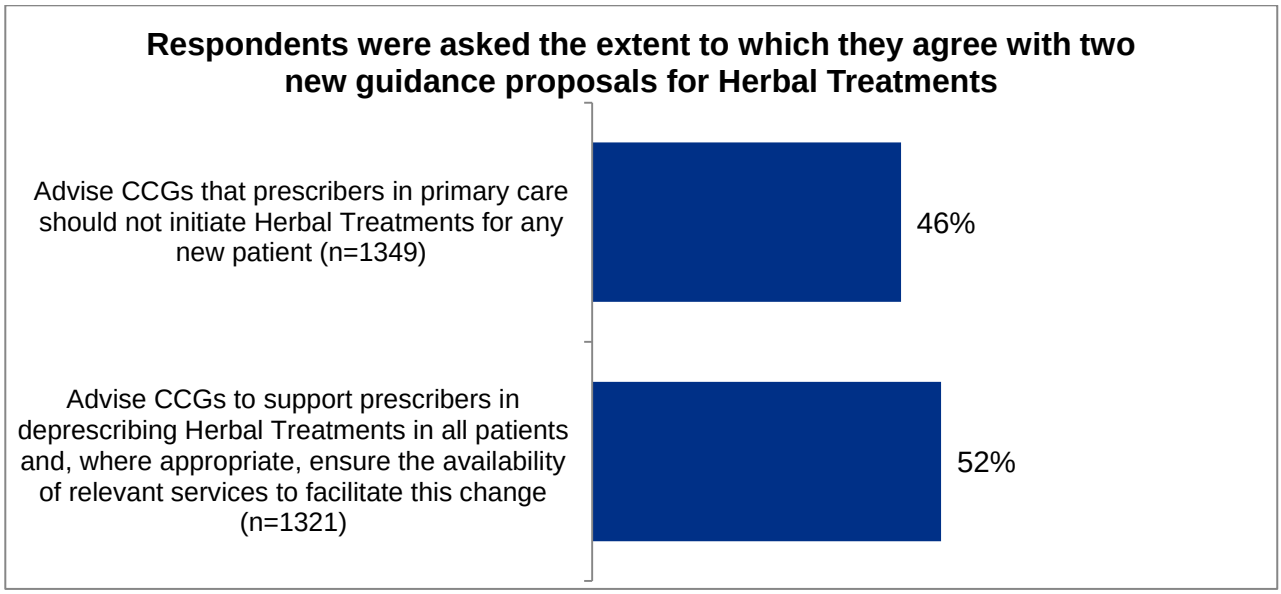
Some call for clearer guidance from NHS England and say the impact on those from a lower socioeconomic background should be considered.

"Limited evidence of its effectiveness and other medications available." (Other healthcare organisation)

4.6 Herbal Treatments

Herbal Treatments are currently available in the UK to help with minor health conditions that do not require medical supervision. This is a very wide category and includes things like St John's Wort, Black Cohosh and Chinese medicines. Herbal Treatments can come in a variety of formulations, such as tablets, capsules, powders and sprays. These items can be bought over the counter. The inclusion of Herbal Treatments within this consultation is due to the lack of robust evidence of their clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'unsure' and 'don't know'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The most commonly mentioned themes from this cohort are that Herbal Medicines are an effective treatment; the proposal goes against the patient's freedom of choice; there is evidence that shows the effectiveness of Herbal Medicines; and this form of treatment is less expensive than orthodox medicines and could save the NHS money compared to alternative treatments and conventional medicines. Alongside this, there is concern that those on low incomes would not be able to purchase these treatments if not provided by the NHS.

"Anthroposophical herbal remedies are very helpful and effective, and it would really limit patient choice if the few anthroposophical doctors who do prescribe on the NHS were to be prevented from doing so."

Members of public and family members

This group's most commonly mentioned themes are also that Herbal Medicines are an effective treatment; the proposal goes against the patient's freedom of choice; there is evidence that shows the effectiveness of Herbal Medicines; and this form of treatment is less expensive. Additionally, this cohort also states there is a low risk of addiction and side effects with this type of treatment.

CCGs

CCGs express their support for the proposal, with individuals stating that these products should be blacklisted. There is also the belief that because there is limited evidence into the effectiveness of this treatment it should not be prescribed by the NHS. This cohort also believes if patients choose to use this form of medication, they should fund it themselves.

“There is insufficient high-quality evidence to demonstrate clinical effectiveness of complementary and alternative medicines. Some complementary and alternative medicines or treatments are based on principles and an evidence base that are not recognised by the majority of independent scientists. There is absolute lack of well-conducted systematic reviews that permits any basic analyses of these therapies.”

Clinicians

Most clinicians state that they agree with the proposals. They state that: the NHS should only be providing evidence-based medicines, side effects and interactions of Herbal Treatments are unknown and herbal treatments are a waste of NHS money and resources

However herbalist clinicians were not supportive of the proposals and state that this is an effective treatment and that there is evidence to support this. Other key themes to emerge amongst this group are that this proposed guidance goes against the patient’s freedom of choice; it would impact on those from lower socioeconomic backgrounds and their ability to afford this treatment if it were no longer available; and that herbal medicines are less expensive than orthodox medicines.

Patient representative organisations, voluntary organisations and charities

The key themes to emerge from this cohort are that Herbal Medicines are effective and could assist in other areas such as antibiotic resistance; they pose less risk of side effects and addiction; the proposal goes against the patient’s freedom of choice; and Herbal Medicines are relatively less expensive.

Some organisations, such as The Nightingale Collaboration, support the proposed guidance outlined for Herbal Treatments citing the lack of evidence for their effectiveness. Humanists UK believe greater education is required to protect patients from this form of treatment.

“Herbal Treatments cost very little, have amazing patient outcomes and could save the NHS money if more widely used. This consultation has not taken on board patient experiences which vouch for effectiveness and how Herbal Treatments can keep drug costs at a minimum. Herbal Treatments offer a solution to the NHS's problems and it would be short-sighted and unscientific to cut Herbal Treatments due to lack of proper evaluation of current NHS services offering said treatments.”

Other NHS organisations, provider organisations and professional bodies

Some bodies state that Herbal Treatments are effective for patients and believe that evidence of this treatment does exist. Other responses from this group support the proposals and doubt effectiveness.

NICE agrees with both recommendations. Although NICE has never been referred to in any guidance around Herbal Treatments, it does have guidance that indicates no evidence of effectiveness in conditions such as endometriosis. The Royal Pharmaceutical Society also supports the recommendations, stating a lack of evidence for the effectiveness of these products which are also freely available over the counter.

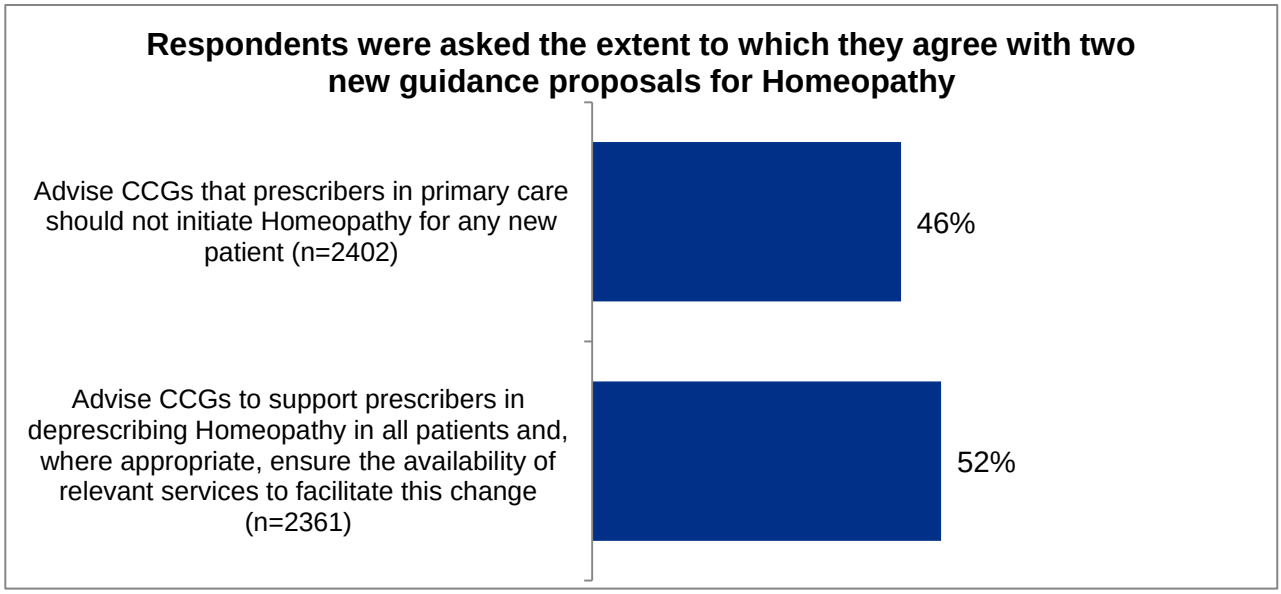
Industry

The main themes to emerge amongst this cohort are that Herbal Medicines are an effective treatment and there is evidence that shows this. This group also states that Herbal Medicines are safer (less risk of side effects and addiction) and cheaper than traditional medicines and healthcare professionals should be given the freedom to advise their patients as to whether they are necessary.

4.7 Homeopathy

Homeopathy seeks to treat patients with highly diluted substances that are administered orally. Homeopathy is mainly available in tablet form but also comes in drops, capsules and powders. These items can be bought over the counter. The inclusion of Homeopathy within this consultation is due to there being a lack of robust evidence for its clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients who responded critically on this item said that in their view homeopathy is an effective treatment; it is cheaper than conventional medicine; it can replace ineffective medicines; the proposal goes against a patient's freedom to choose their treatment; and homeopathic treatments save the NHS money.

"Homeopathy works for a lot of people. Even if this is only the placebo effect shouldn't it not be explored? After all, the placebo effect is free!"

Members of the public and family members

This group makes similar comments to patients with most saying it is ineffective and some saying it is effective. Reasons given against homeopathic treatment include the lack of proven evidence and that they are a waste of NHS money.

"Homeopathy has been demonstrably disproved. Starting from a position of implausible benefits from diluted ingredients, the overwhelming negative evidence should be enough for any reasonable person to see that this is a con."

CCGs

CCGs are in full support of the proposals. They say that homeopathy products should be blacklisted, there is a lack of proven evidence, and the NHS should prioritise evidence-based medicines and treatments.

"These should be blacklisted to enable a consistent and equitable approach across the country on these medicines of very limited clinical value."

CCGs recognise there is no benefit beyond a placebo effect but some say that placebo can be a useful tool in exceptional circumstances.

"*We consider that Homeopathy is no more than a placebo which should not be available at NHS expense. A patient leaflet should be produced explaining the reasons why it is not available on the NHS to counter the mystical science that is advertised alongside these products.""*

Clinicians

Comments were received from Homeopathic clinicians and orthodox medicine clinicians and reflect both sets of views. Homeopathic clinicians give similar views to patient respondents. Conventional clinicians are either in favour of the proposals (due to lack of clinical evidence and therefore inappropriate for NHS money to be spent on this) or say that homeopathic medicines are harmless and their benefit is as a placebo.

"Prescribing Homeopathic products seems to me a clear breach of Good Medical Practice. It is shambolic that in this day and age the NHS is still paying for such sham treatment."

"Homeopathy has been conclusively shown to be of no benefit for any medical condition via detailed meta-analyses of many clinical trials. The mechanisms of efficacy promulgated by Homeopathy advocates lack prior plausibility – to accept them would require ignoring large chunks of chemistry and biology. It is utter bunkum and a waste of taxpayers' money to fund such quackery."

"I am a GP of more than 30 years' experience and also use Homeopathy at times within my practice … I tend not to offer Homeopathic medicines if there is a safe, effective and acceptable conventional treatment available but for many forms of distress I see in my patients, conventional treatments may be ineffective or not acceptable."

Patient representative organisations, voluntary organisations and charities

This cohort of respondents is against the proposal. Responses were mainly from societies and associations in favour of homeopathy. They make the same comments as the patients.

Other NHS organisations, provider organisations and professional bodies

This group includes Homeopathic organisations which are against the proposals for reasons already given (see above) – such as the Society of Homeopaths, Homeopathy Research Institute, and British Homeopathic Association. Responses from other NHS organisations, provider organisations and professional bodies including NICE, BMA, Royal Pharmaceutical Society, Association of the British Pharmaceutical Industry, Humanists UK, The Royal Society, the Academy of Medical Sciences and the Good Thinking Society, are in agreement with the proposal.

NICE agrees with both recommendations. They note that they have never been referred any guidance topics specifically on Homeopathic treatments. NICE has produced guidance where the evidence shows no evidence of effectiveness across a range of conditions, including otitis media, lower urinary tract symptoms in men, induction of labour, neonatal jaundice and eczema.

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. (Royal Pharmaceutical Society)

[Homeopathy is] better dealt with by inclusion in the blacklist of drugs unavailable on the NHS. (British Medical Association)

NICE has never been referred any guidance topics specifically on Homeopathic treatments, and therefore they have not been the subject of a specific NICE evaluation. However, NICE has produced guidance where the evidence shows no evidence of effectiveness across a range of conditions, including otitis media, lower urinary tract symptoms in men, induction of labour, neonatal jaundice and eczema. (NICE)

Industry

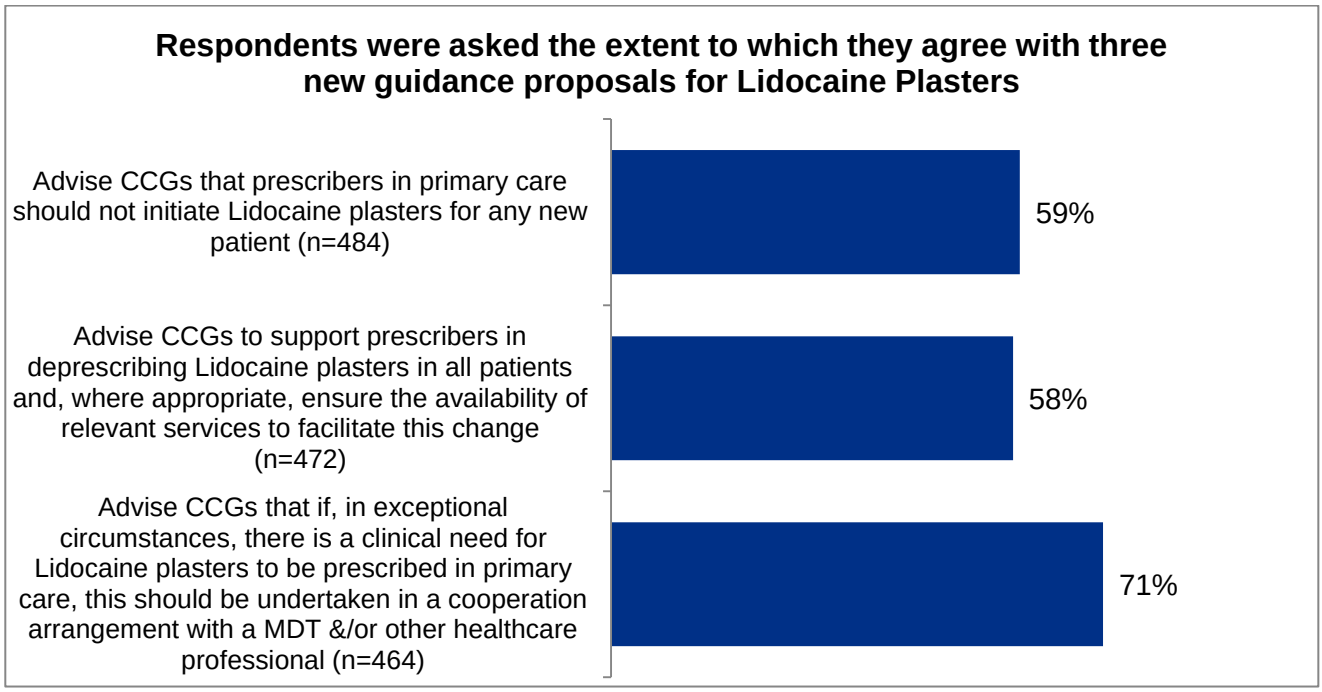
The only response was from the Association of the British Pharmaceutical Industry which welcomes the proposal to stop prescribing Homeopathic remedies that have not been subject to the same stringent conditions required of licensed medicines.

4.8 Lidocaine Plasters

Lidocaine Plasters (patches) can be applied for pain relief and are licensed for symptomatic relief of neuropathic/ nerve pain associated with shingles in adults. NICE guidance does not recommend Lidocaine Plasters for treating neuropathic pain. Due to its non-inclusion in NICE guidance, the group considered Lidocaine Plasters suitable for

inclusion in the consultation.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key themes emerging from patient comments are: that Lidocaine Plasters are an effective treatment; the guidance should consider the impact on the patient's quality of life if this treatment is removed and the impact on patients who are unable to take alternative medicine; and cost should not be considered when decisions are being made around the prescription of Lidocaine Plasters. Some also query the use of evidence and guidance from sources like PrescQIPP and NICE and the consistency with NHS England views.

"If the patches are withdrawn, there needs to be a viable alternative. Surely it is better to prescribe something that has little side effects and provides excellent pain relief, than anti inflammatories and pain killers that a patient can build up tolerance to or have side effects that can impact on health in the future. This could end up costing the NHS more if side effects cause medical problems …"

Members of the public and family members

This group raises similar comments to patients. Their key themes in response to this proposal are: that it is an effective treatment; the effect on patients' quality of life and

those who are unable to take alternative medications should be considered; and there should be clearer guidance around use in exceptional circumstances. A small group feel this treatment should be blacklisted.

"My sister has been chronically Ill and needs a high level of pain relief, other painkillers did not work. These have meant she had a higher quality of life and can get out and about. If you see someone in awful pain you wouldn't not help them, you know these are vital for some people."

CCGs

Although some feel this is an effective treatment, the majority of CCGs are in agreement with the proposed guidance. Additional themes to emerge amongst this group include: Lidocaine Plasters should be blacklisted; further clarification is required around use in exceptional circumstances; the prescribing process should involve input from both primary and secondary care professionals, and prescription should only be restricted to the conditions Lidocaine Plasters are indicated for as currently it is being used outside of its product license.

"There should be no need to prescribe within primary care under the licensing and NICE guidance. Prescribing is short-term in limited patient groups and therefore should be prescribed via secondary care only."

Clinicians

Clinicians say that Lidocaine Plasters are an effective treatment for a niche group of patients, i.e. palliative care and cancer patients. They also highlight that the prescription of this treatment should involve both primary and secondary care professionals.

"I accept that they are very much for a niche only, and I have only had to use them in two or three patients, but in those patients where nothing else was working, they have been extremely effective."

Patient representative organisations, voluntary organisations and charities

This cohort feels Lidocaine Plasters are an effective treatment for a niche group of patients so should not be deprescribed. Rather, prescriptions should be reviewed and the efficacy of treatment monitored by specialist teams and coordinated with primary care.

Other NHS organisations, provider organisations and professional bodies

Organisations make a range of comments, including: that Lidocaine Plasters are effective; they should be blacklisted; the prescription process should be reviewed; and a more coordinated approach between primary and secondary care professionals should be implemented.

NICE agrees with all three of the proposals, also noting that when exercising their judgement, health professionals are expected to take the guidance fully into account alongside the individual's needs.

The Royal Pharmaceutical Society and the British Medical Association do not support the proposals. They cite similar reasons around it being inappropriate to deprescribe in patients who have seen a good therapeutic response to treatment.

*"This is approved on the formulary for focal neuropathic pain with allodynia, and for PHN where patients cannot tolerate oral medicines. For some patients this is invaluable as can reduce escalating doses of other analgesics with systemic ADRs which can cause significant problems. The Trust want to continue to be able to ask GPs to prescribe in those patients benefitting from treatment when being used for the criteria for use that is locally agreed. There is also some use in post-operative patients as part of multimodal analgesia (to assist opioid dose reduction and faster discharge), but it is reasonable to expect that ongoing supplies are not requested from the GP." (*NHS Provider Organisation)

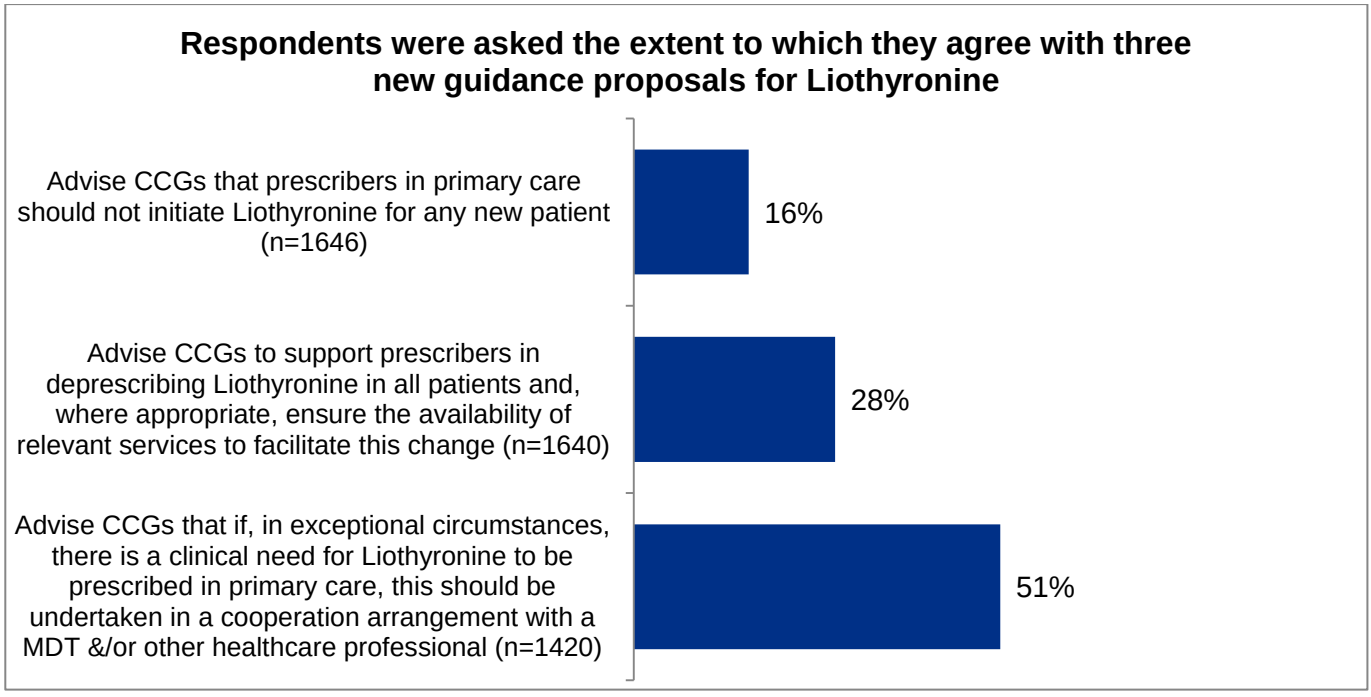
Industry

Grünenthal Ltd states Lidocaine Plasters are an effective treatment for a number of conditions. In relation to the proposed guidance, there is some concern around the impact on pain and palliative care patients and the fact that restricting prescribing will disadvantage patients as these are not available over the counter, forcing patients to attend hospital clinics to obtain a prescription.

4.9 Liothyronine

Liothyronine is used to treat Hypothyroidism (when the thyroid produces less thyroid hormone than it should). It has a similar action to Levothyroxine but is more rapidly broken down in the body and has a more rapid effect. Liothyronine is available as a tablet and also available as Liothyronine + Levothyroxine combination products e.g. Armour Thyroid.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients raise a number of concerns against the proposal including: that Liothyronine is an effective treatment: the impact on those with a genuine clinical need; before deprescribing the product the quality of life for Hypothyroid patients must be considered if treatment is removed; and that Liothyronine is cheaper abroad but very expensive privately in the UK.

"One only has to go onto the Thyroid UK website to find a world of patients who self-medicate and arrange their own blood tests because they feel so unwell taking Levothyroxine only. As both a patient and a registered nurse I cannot believe that there is such gross unawareness of the need for Liothyronine. For years I was needlessly suffering severe symptoms and would have been unable to continue working as a nurse had I not started self-medicating with Liothyronine – when I did my symptoms fled and within 20 minutes of taking it I had my energy and life back – it is simply not true that Levothyroxine does the same thing."

Members of the public and family members

This cohort raises the same concerns as patients. They also say that there should be better knowledge amongst healthcare professionals around Hypothyroidism so they understand when and how to prescribe Liothyronine.

CCGs

CCGs make a range of comments including: little support for allowing prescribing in exceptional circumstances; that the treatment should be blacklisted; the proposal is based on cost; and if prescribing is stopped no one should be allowed to access it. They also requested clear guidance on what constitutes exceptional circumstances.

"Our CCGs have been actively pursuing a reduction in Liothyronine prescribing in recent months. It has become apparent that local endocrinologists and head and neck clinicians are willing to continue to support some patients who petition for continued treatment with Liothyronine and so the support of a multi-disciplinary team has not led to a discontinuation of the medication … If prescribing is to be allowed to continue, there should be clear guidance in terms of the thyroid function test results and significant pressure on manufacturers to reduce the price to a reasonable level. At a lower cost, there would be less need to pursue deprescribing of a medication that some patients feel very strongly have had a positive effect on their quality of life."

Clinicians

Comments from clinicians reflect the view that Liothyronine should be available for new patients but that the product should be available in exceptional circumstances and to support prescribers in deprescribing. Their comments focus on: the effectiveness of the

treatment; the need to improve knowledge about Hypothyroidism amongst GPs/healthcare professionals and allow them to prescribe Liothyronine; blacklisting the product; and if treatment is removed, no-one should be allowed to access it.

Patient representative organisations, voluntary organisations and charities

Organisations representing patients with Thyroid conditions that disagree with the proposals include: British Thyroid Association, Thyroid UK, Improve Thyroid Treatment (ITT) Campaign, and Thyroid Association of New Zealand Incorporated. The Patients Association also felt that patient concerns about the proposals should be considered. Feedback from these organisations reflects themes in patient responses.

Other NHS organisations, provider organisations and professional bodies

This group mostly disagrees with the proposals. Those disagreeing include the Royal College of Psychiatrists, Royal Pharmaceutical Society, British Medical Association (BMA state that it should be consultants and not primary care making deprescribing decisions) and the British Generic Manufacturers Association (they believe new generic entrants will make Liothyronine cost-effective for discrete groups of patients).

Other comments made by organisations include: that Liothyronine is an effective treatment; there is a need for more testing and research to prove effectiveness; there needs to be better knowledge and understanding amongst healthcare professionals around Hypothyroidism to enable better prescribing as well as clearer guidance on what constitutes ‘exceptional’; and that the proposal is based on cost.

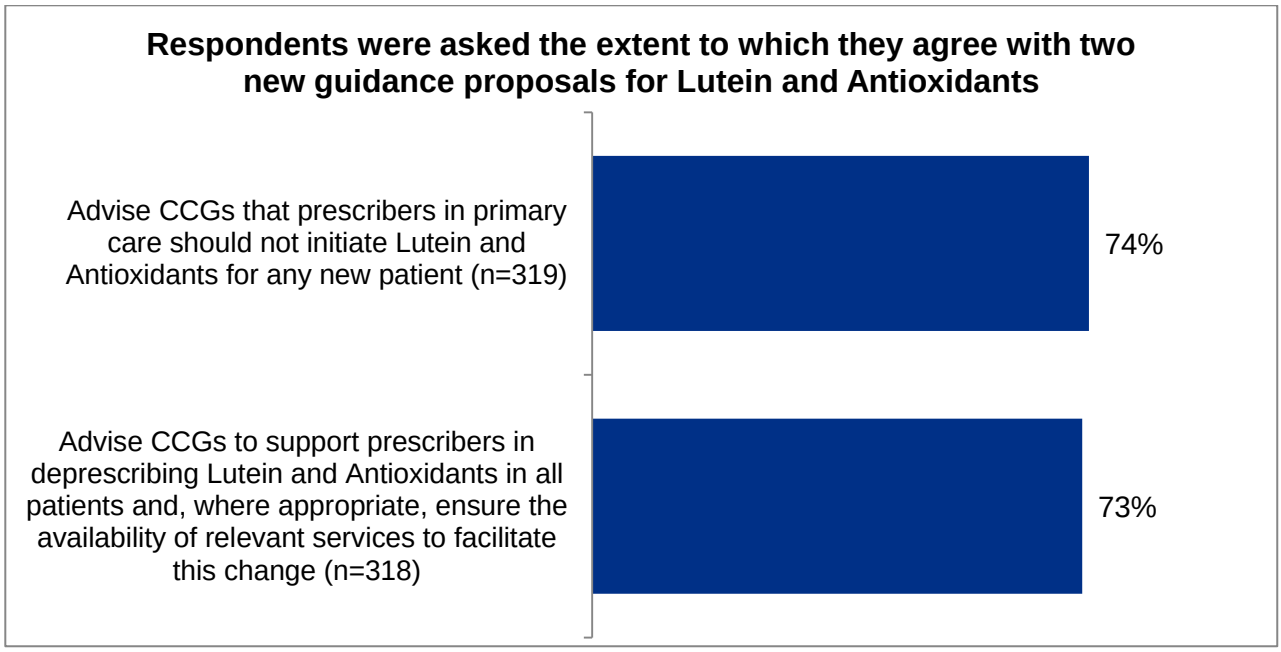
Industry

Industry respondents support the continued prescribing of Liothyronine in accordance with NICE guidelines which state that T3 is not initiated in primary care but “*may be considered by endocrinology specialists… in people who have persistent symptoms despite compliance with Levothyroxine treatment and a TSH value in the normal range.”* (https://cks.nice.org.uk/hypothyroidism#!scenario)

4.10 Lutein and Antioxidants

Lutein and Antioxidants (e.g. vitamin A, C, E and zinc) are supplements recommended for age-related macular degeneration (AMD; a condition that causes loss of central vision, usually in both eyes). PrescQIPP CIC has issued a bulletin which found no evidence to support routine prescribing of Lutein and Antioxidants. These items can be bought over the counter.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients say Lutein and Antioxidants are effective treatments and there is evidence to support this. They say it is considered to be beneficial in cases where patients suffer from age-related macular degeneration. A chief concern raised is that people on low incomes would find it difficult to afford these supplements if they were removed from prescriptions.

"From my own experience, I believe that the use of Lutein supplements (Occuvite in my case) has helped to stabilise my vision and probably reduce the number of injections needed. However these supplements are expensive to buy privately."

Members of the public and family members

Members of the public also feel that Lutein and Antioxidants are effective treatments and there is evidence available that show the effectiveness. They also say the impact on people with low incomes should be considered.

CCGs

CCGs make comments in agreement with the proposals and say that there is very limited or insufficient evidence to demonstrate the effectiveness of Lutein and Antioxidants and that patients should purchase these supplements over the counter if they want them.

"Could be purchased over the counter. The CCG supports self-care for this type of product."

Clinicians

Clinicians raise concerns about the limited evidence to demonstrate the effectiveness of Lutein and Antioxidants.

Patient representative organisations, voluntary organisations and charities

These organisisations make similar comments to patients and the public, highlighting the effectiveness of this product.

"I have personal experience of the positive effects of taking Macushield. OCT results show improvements in my eye health during the time I have been taking this medication. My doctor refused to prescribe it last year and since then I have funded this myself, because as a full-time carer for a disabled husband I cannot afford to go blind, but I am also struggling to pay to fund it. Imagine the cost to the health and social care budget if I did go blind, not only would it be devastation for me personally but there would be two people who would need full-time care. Not cost-effective." (Voluntary organisation or charity)

Other NHS organisations, provider organisations and professional bodies

Other NHS organisations agree with the recommendations saying that: the NHS should only provide evidence-based medicines, there is a lack of proven evidence showing the effectiveness of Lutein and Antioxidants, and that the treatment is available over the counter.

"Lutein and Antioxidants are included in our local prescribing for clinical need policy and are not recommended for prescribing because of the lack of evidence relating to their efficacy and cost effectiveness." (other NHS organisation)

The Royal Pharmaceutical Society agrees with the recommendations. The British Medical Association says it would be better dealt with by blacklisting this item.

Industry

The one industry body to comment on the recommendations disagrees with them and is concerned that if the treatment is not available it may lead to wider health problems.

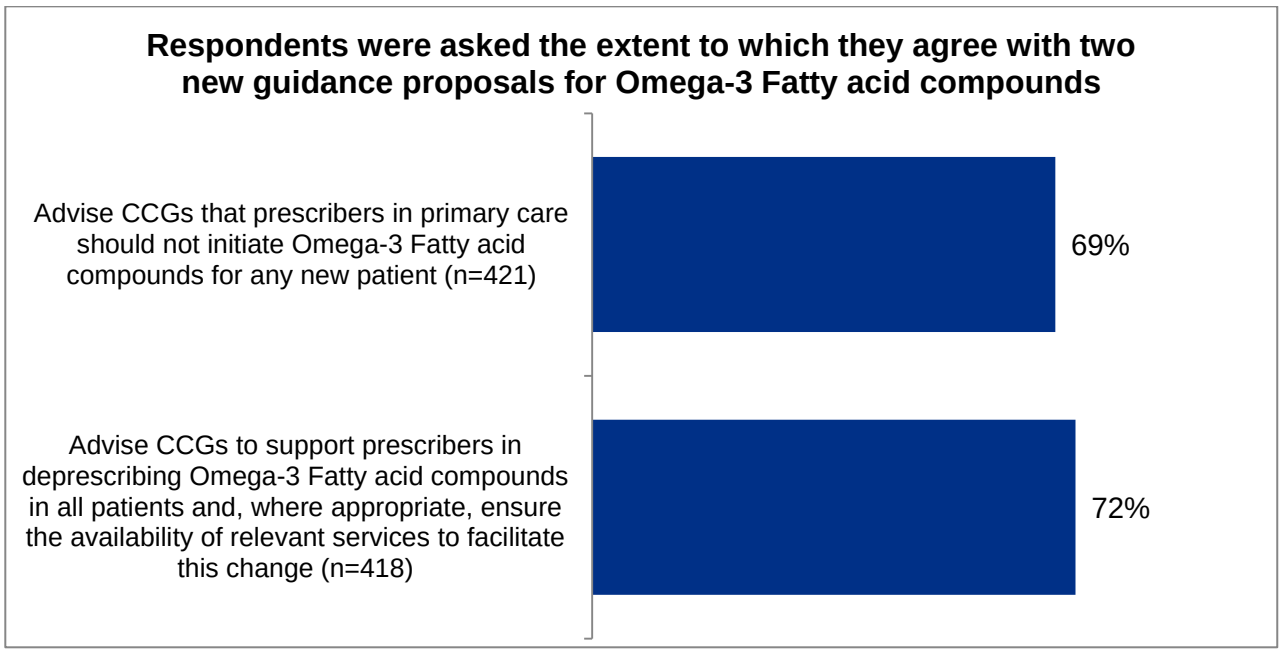
"Food supplements should not be ignored as a potential health benefit in those where pharmaceutical agents don't exist, are not preferred by the patient, and could be cheaper than managing the latter consequences of possible poor health."

4.11 Omega-3 fatty acid compounds

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 hypertriglyceridemia; adjunct to diet in type IV hypertriglyceridemia and adjunct in secondary prevention in those who have had a myocardial infarction in the preceding three months. Omega-3 fatty acid compounds are available as capsules under the brand name Omacor or Prestylon and can be bought over the counter. There is no good quality data for their use in prevention of dementia, pre-menstrual syndrome, attention-deficit hyperactivity disorder (ADHD), atrial fibrillation, eczema, osteoarthritis or age-related macular degeneration. The

inclusion of Omega-3 fatty acid compounds within this consultation is due to there being a lack of robust evidence for clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Some patients comment on the effectiveness of Omega-3 fatty acids, the availability of the product over the counter, and that public/patient communication or education is required to explain how these compounds can be gained through a balanced diet.

"Omega-3 is available over the counter probably a lot cheaper than on prescription."

Members of the public and family members

This group makes similar comments to patients noting that Omega-3 fatty acid compounds are an effective treatment for a number of conditions, they are readily available over the counter and emphasis/communication is needed on the importance of eating a balanced diet.

CCGs

Most CCGs are in full support of the proposals and say that prescribing of all Omega-3 fatty acid compounds should be stopped, not least because they are readily available

over the counter and there is lack of clinical evidence.

"These should be added to the blacklist due to lack of clinical evidence."

Clinicians

Again most comments are in agreement with the proposals, suggesting blacklisting of the treatment and mentioning its availability over the counter. However, some clinicians also cite its effectiveness for a number of conditions.

"At clinical doses and with good and pure formulas, Omega-3 oils have been shown to be very effective. It reduces inflammatory-type responses which tend to be the root cause of most disease. It is not harmful and has far better health implications than other anti-inflammatory-type drugs. Helpful for pain, blood cholesterol levels, dementia etc."

Patient representative organisations, voluntary organisations and charities

Most of these groups agree with the principles, making comments similar to those raised by patients and the public. One organisation comments that taking Omega-3 is a lifestyle choice, and should therefore be funded by the patient.

Other NHS organisations, provider organisations and professional bodies

Some organisations are supportive of the proposals and some say that the product should be blacklisted. However, some feel it is an effective treatment for a number of conditions.

"NHS England should issue clear, national advice on how changes should be made and how to transition to alternative products. This will enable clear advice to be followed in primary care, reducing the need for secondary care involvement… The committee has some concerns that the guidance is largely focused on primary care prescribing and not secondary care. It is felt that this still leaves an open door for prescribing these items and while it is recognised that they might need to be prescribed in specific cases, they shouldn't be used in the vast majority of patients in any sector." (Other NHS organisation)

"The 'do not do' recommendations are accepted; however these are agreed on formulary in SE London for management of hypertriglyceridemia for use where fibrates are not tolerated (not covered by the 'do not do' recommendations). The recommendation should be explicit that usage for this indication may be appropriate, and a blanket rule of not prescribing in primary care is therefore not helpful as patients appropriate for treatment may struggle to receive it." (NHS provider organisation)

NICE, the North Central London Medicines Optimisation Committee and the Royal Pharmaceutical Society are amongst those who support the proposals, with the Royal Pharmaceutical Society commenting that the products are readily available to buy for patients who choose to supplement their treatment in this way.

The British Medical Association feels that Omega-3 fatty acid compounds would be better dealt with by inclusion in the blacklist of drugs unavailable on the NHS.

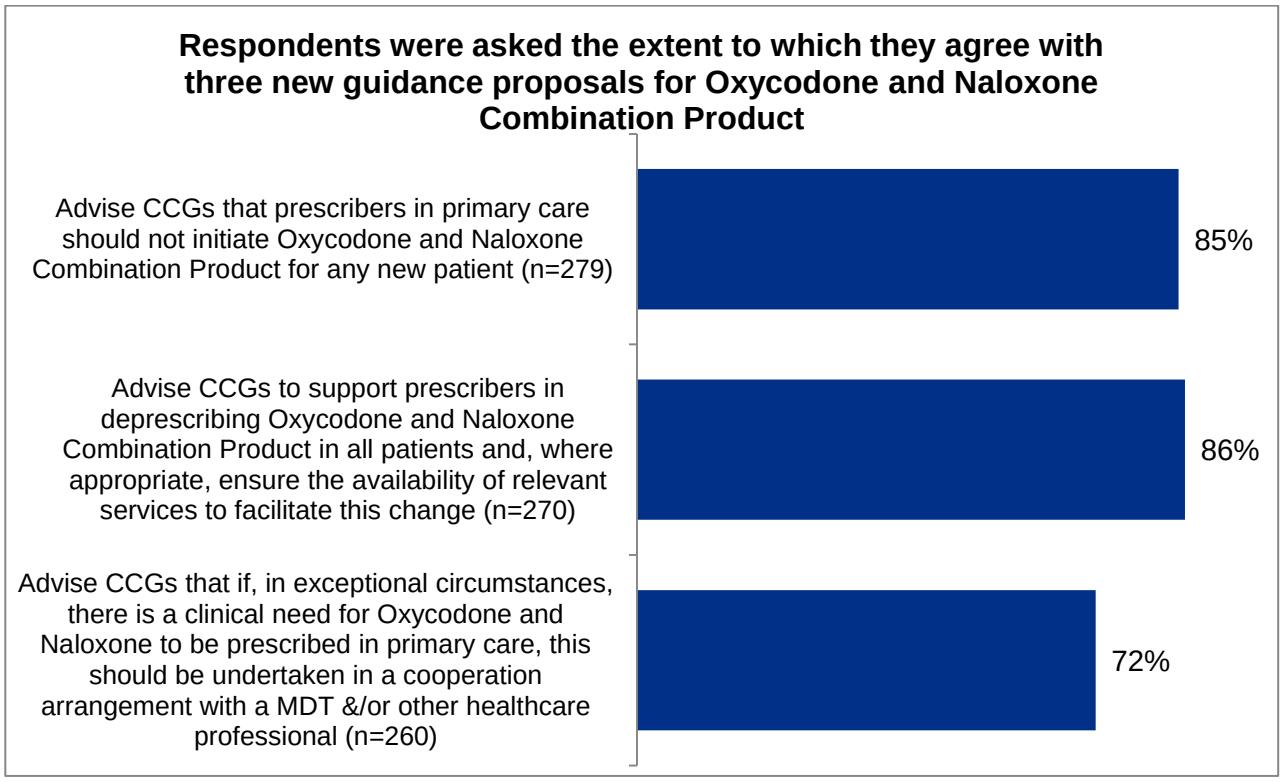
Industry

Just one industry responded to the consultation; they are in full support of the proposals.

4.12 Oxycodone and Naloxone combination product

Oxycodone and Naloxone Combination Product is available under the brand name Targinact and is used to treat severe pain. The inclusion of Oxycodone and Naloxone within this consultation is due to the fact that there is no clear benefit of this single treatment over other painkillers that are combined with laxatives when required. The product is also considered suitable for inclusion due to its significant cost and unclear role when compared with individual products.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The comments raised by patients include: that this product is an effective treatment for a small group of patients; the need to consider patients for whom other medications (e.g. morphine, opiate-based drugs) are ineffective; and that prescribing of this product requires a coordinated approach between primary and secondary care:

"As a former Palliative Care healthcare assistant, Oxycodone and Naloxone are useful in

patients with advanced cancer. I am of the view that it should only be made available to patients on Palliative Care grounds. It should not be made available to any other users as there is no clinical need."

Some note that there are safety concerns with Oxycodone and Naloxone in relation to side effects or addiction.

Members of the public and family members

This cohort agrees that there are safety concerns with Oxycodone and Naloxone but that it is an effective treatment for a small group of patients.

CCGs

CCGs support the medications being added to the blacklist as alternative treatments are available and there is a lack of proven evidence showing the effectiveness of Oxycodone and Naloxone, and no-one should be allowed to access the treatment.

"It needs to be consistent and the only way is by blacklisting. This removes duplication of time and effort at CCG level."

Clinicians

Clinicians say that this combination product is not required and can be prescribed as separate products. They also say that the treatment should only be prescribed by specialists and secondary care and acknowledge that it is an effective treatment for a small group of patients.

"Traditional laxatives are not always effective or tolerated by patients and so there are occasions when this drug is the only option. It needs to be used in moderation and when all other efforts have failed. However should not be deprescribed as a blanket rule, needs to be assessed on a patient-by-patient basis."

Some clinicians say that they would support the product being added to the blacklist.

Patient representative organisations, voluntary organisations and charities

One respondent says that Oxycodone and Naloxone is an effective treatment for a small group of patients. Another suggests that patients for whom other medications are ineffective should be considered for it.

"Finding the best pain relief combinations for patients can be a difficult exercise and an individualised approach to prescribing is needed in order to accommodate the needs and sensitivities of different patients to different medications and combinations of medications. Removing this drug combination as an option would be counter-productive as it will leave some without effective pain relief or with considerable side effects."

Other NHS organisations, provider organisations and professional bodies

Several respondents say that the combination product is an effective treatment for a small group of patients. Others urge NHS England to consider the quality of life for patients who require Oxycodone and Naloxone, including availability for palliative care patients.

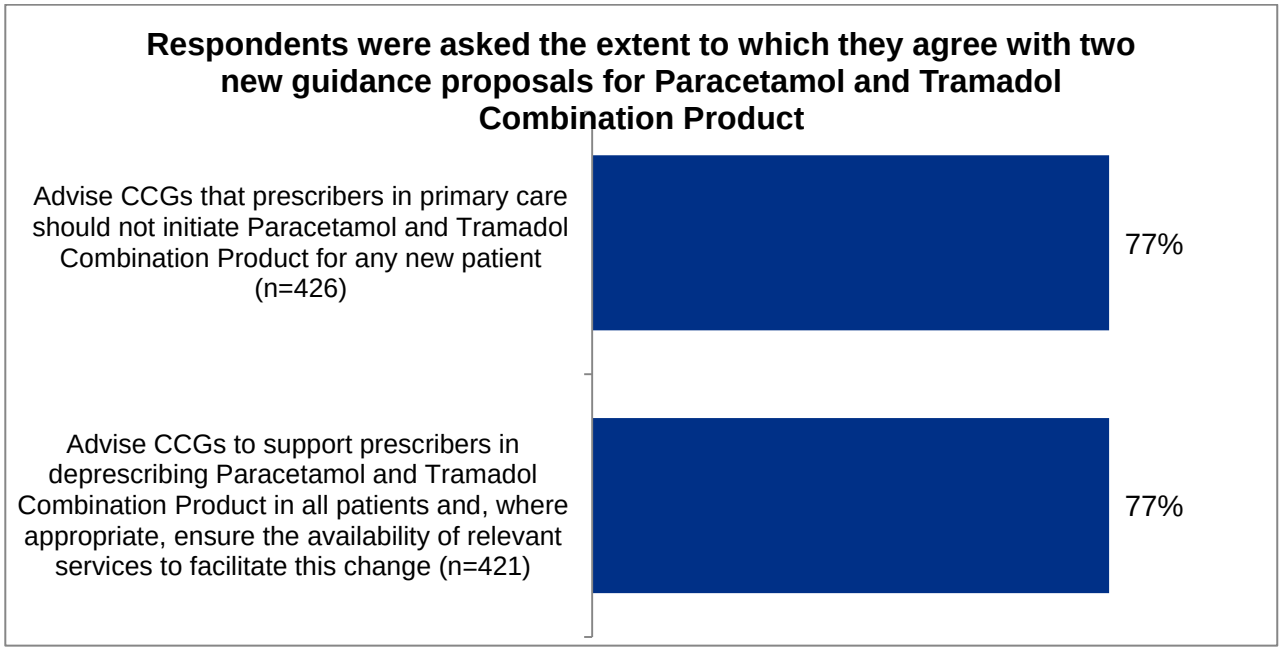
The British Medical Association argues that for terminally ill patients who experience

severe constipation on opioids, the combination of Oxycodone and Naloxone can greatly improve their quality of life.

4.13 Paracetamol and Tramadol combination product

Paracetamol and Tramadol are both commonly available painkillers. This recommendation relates to where both chemical ingredients are used together in a single combination product. They are available as tablets and effervescent tablets, with the brand name Tramacet. Paracetamol and Tramadol combination products are more expensive than the products with the individual components. They are included in this consultation because there are more cost-effective products available.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key themes raised by patients include: the ready availability of Paracetamol at a low cost over the counter and safety concerns in relation to side effects or addiction. The key theme against the proposal focuses on the effectiveness of this combination treatment, particularly for those who have difficulty in taking other treatments.

"I also object to the removal of pain killers. As someone who suffers chronic pain I can tell you that many medications can be intolerable to patients with complex conditions,

or interact badly with other meds/symptoms and so choice is necessary. Additionally there are many types of pain that only different types of painkiller can help."

Members of the public and family members

Like patients, a common theme raised by this cohort is around the availability of some of the individual components over the counter at low cost. Additional themes in support of the proposal also include the suggestion to blacklist this product and that taking Paracetamol and Tramadol separately is more effective.

The key themes against the proposal focus on the effectiveness of the treatment, particularly for those who have difficulty with other treatments and concern regarding the impact on the quality of life should this be removed.

Comments are also made around the implementation of the proposal, such as the need for clearer guidance on what constitutes 'exceptional circumstances'.

CCGs

The key themes raised by CCGs include: blacklisting this product; and that some of the individual components (Paracetamol) are available at low cost and that taking them separately is more effective. There are also comments relating to the need for clearer guidance from NHS England to implement this effectively.

"It should be blacklisted in the Drug Tariff."

Clinicians

Clinicians raise similar themes to CCGs: that this product should be blacklisted; that some of the individual components (Paracetamol) are available at low cost and effective when taken separately; and that alternatives are readily available.

On the contrary, the key theme to emerge against the proposal is around the fact that this combination product is an effective treatment.

"Separate prescribing allows more versatility in dosing both for providers and patients. It should also be possible to deliver this medicine at a lower cost this way."

Patient representative organisations, voluntary organisations and charities

The key themes in favour of the proposal include: safety concerns with the use of this combination product and the availability of some of the individual components over the counter (Paracetamol). The key themes against the proposal focus on the need to consider the impact on those in lower socioeconomic groups.

Other NHS organisations, provider organisations and professional bodies

The common themes in support of the proposal amongst this cohort relate to availability of some of these products at a lower cost (Paracetamol), safety concerns and that the treatment should be blacklisted and no longer prescribed.

Other key themes amongst this cohort include: the need for clearer guidance on what constitutes exceptional circumstances and the recommendation to lift restrictions on the amount of Paracetamol that can be purchased over the counter.

"This product is available as individual components which are cheaper than the combined version." (Other NHS organisation)

Industry

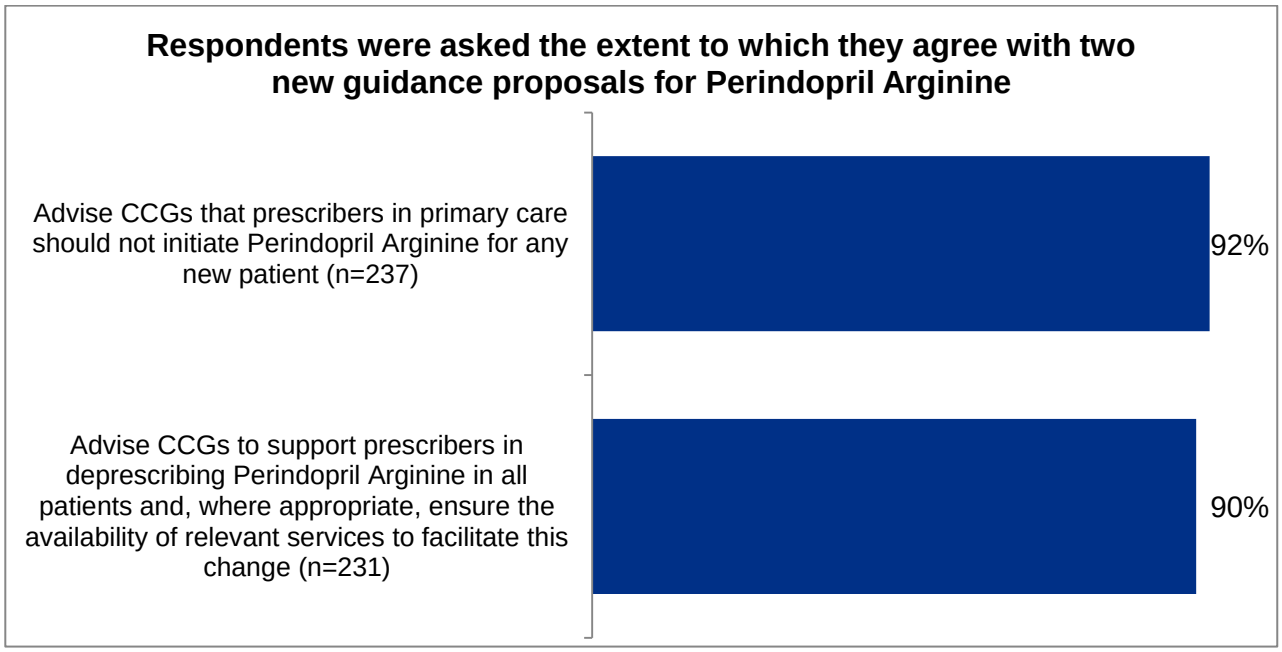
The key themes raised by industry bodies include the availability of suitable alternatives at low cost to the NHS, the effectiveness of taking these products separately and also the possible impact on market dynamics and costs should this product be removed.

"Agree that there may be suitable alternatives, however for those patients who are currently on treatment; to be continued with support."

4.14 Perindopril Arginine

Perindopril Arginine 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. Perindopril Arginine is available as a tablet, under the brand name Coversyl Arginine, and is also available as a combination with a diuretic (water table) as Coversyl Arginine Plus. Perindopril Arginine is included in the consultation because it is significantly more expensive than Perindopril Erbumine and there is no clinical advantage of the Arginine Salt.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key themes raised by patients supporting the proposal include the availability of suitable alternatives and that the treatment should be blacklisted. The key themes not in favour of the proposal include: that it is an effective treatment; it should be available to those unable to tolerate alternative treatments; and that the proposal does not take into account evidence showing its effectiveness.

"This medication controls my blood pressure better than other types of medication. I have taken it for many years without side effects. I don't want to have to start having to try various medications to find one that suits me."

Members of the public and family members

This cohort raises the same themes as patients in support of and against the proposal. The key themes supporting the proposal include the availability of alternatives and that the treatment should be blacklisted. The key themes raised against the proposal include: that it is an effective treatment and that it should be available to those unable to tolerate alternatives.

"It is dangerous having two products with different salts but very different in price as a mix up could be easy to do and different treatment for patients, maybe even cause hospitalisation if patient is sensitive to products."

CCGs

The key themes raised by CCGs include: the treatment is not required; alternatives are available and the guidance should be expanded to include secondary care.

Comments not in favour of the proposal focus on the fact that this is an effective treatment.

Another theme to emerge amongst CCGs is the suggestion that the Arginine Salt is an attempt by the manufacturer to negate the generic market and extend the life of their product.

"Agree that there may be suitable alternatives however for those patients who are currently on treatment; to be continued with support."

Clinicians

Similarly to CCGs the key themes to emerge amongst clinicians include: the fact that the treatment is not required; there are suitable alternatives available; the product should be blacklisted; and there is a need to expand the guidance to include secondary care.

The key theme raised against the proposal is that it is an effective treatment.

Other NHS organisations, provider organisations and professional bodies

Again the key themes from this cohort call for the expansion of the guidance to include secondary care and state that the treatment is not required and there are suitable

alternatives available.

The key theme not in favour of the proposal focuses on the fact that this is an effective treatment.

"NHS England should issue clear, national advice on how changes should be made and how to transition to alternative products. This will enable clear advice to be followed in primary care, reducing the need for secondary care involvement. There is a risk that prescribing will be transferred to secondary care unnecessarily and as such the clear guidance mentioned previously should articulate the relevant clinical strategies. This should be done once at a national level to provide clear support to this change." (Other NHS Organisation)

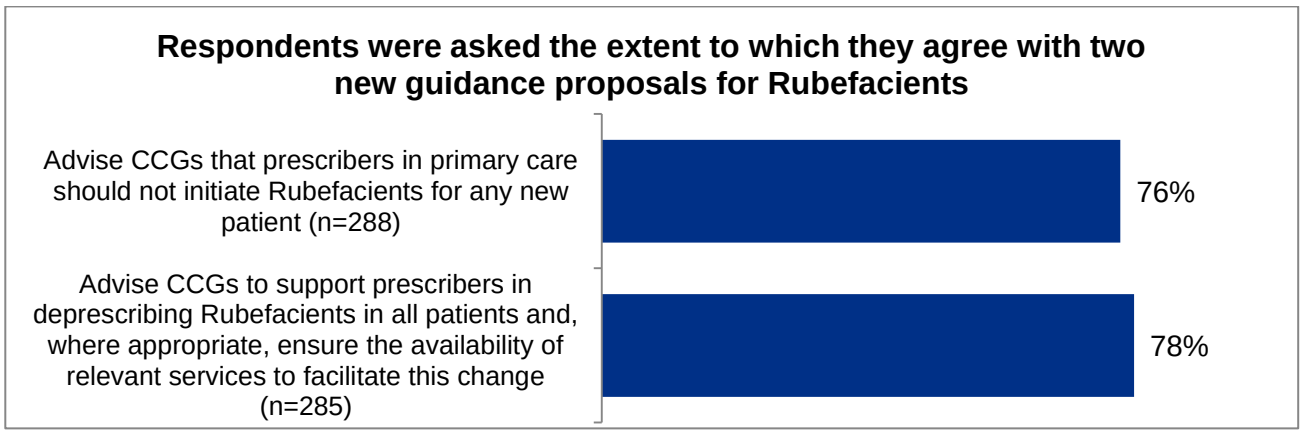
Organisations supporting the proposals include NICE and the Royal Pharmaceutical Society. NICE also notes that when exercising their judgement, health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in NICE guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

The BMA would prefer to see the product blacklisted so they are unavailable on the NHS.

4.15 Rubefacients

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 are currently available as ointments, creams, lotions and sprays. The inclusion of Rubefacients within this consultation is because of their low clinical effectiveness.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key theme raised in support of the proposal relates to the availability of this treatment over the counter at a low cost.

The key themes not in favour of the proposal include: Rubefacients are an effective treatment; removal will have a negative impact on quality of life for patients, including vulnerable groups; and the decision to prescribe should be left to GPs and healthcare professionals.

"Perfectly good over the counter products available. No need to prescribe."

Members of the public and family members

The key themes demonstrating support for the proposal amongst this cohort include: this treatment is readily available over the counter; use of this treatment should be funded by the patient rather than the NHS; Rubefacients should be blacklisted; and there is a lack of evidence demonstrating the effectiveness of the treatment.

The key themes opposing the proposal focus on the effectiveness of the treatment and that GPs and healthcare professionals should be left to decide whether to prescribe it.

CCGs

Key themes mentioned by CCGs indicate support for the proposal. Themes indicate a belief that these treatments should be blacklisted and that they are readily available over the counter at a low cost. A key theme raised that is not in support of the proposal is that Rubefacients can be suited to some patients not suited to other medications.

An additional theme raised by this cohort focuses on the effect of the proposed changes, such as the potential increase in the prescription of alternatives which would negate any potential savings

"Rubefacients should be blacklisted and should no longer be available to prescribe via the NHS. The medicines should be placed on the Drug Tariff blacklist. Within our CCG we have deprescribed Rubefacients and identified alternatives. However patients are still aware that other CCGs have not taken this action. It needs to be consistent and the only way is by blacklisting. This removes duplication of time and effort at CCG level."

Clinicians

Key themes in support of the proposal include: the lack of evidence demonstrating the effectiveness of Rubefacients; availability of alternatives; and the suggestion to blacklist these products.

Key themes not in support of the proposal include: that these are more effective and safer than other treatments; and the potential increase in the prescription of alternatives which would negate any potential savings

"Whilst I agree that Rubefacients have limited efficacy for osteoarthritis, there is longstanding evidence to show their tremendous efficacy in rheumatoid-arthritis,

rheumatism and especially in chronic acute rheumatism. This is especially of worth in children, adolescents as well as adults and the elderly as a safe alternative to NSAIDs (oral or topical) and oral analgesics which are often less effective…"

Patient representative organisations, voluntary organisations and charities

The key theme to emerge from this group is the need to conduct further research to see which form of the compound is most effective and/or provides the greatest cost benefit.

Other NHS organisations, provider organisations and professional bodies

Whilst there is acknowledgement that Rubefacients are an effective treatment the key themes to emerge from this group focus on the concerns around the effectiveness of these treatments and accompanying evidence that demonstrates this and the need for clearer guidance relating to the implementation of the proposal.

NICE and the Royal Pharmaceutical Society support the proposal. NICE specifically highlights that health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients. They endorse that healthcare professionals are to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

"We are concerned that GPs will be pressured to prescribe and will therefore prescribe a topical NSAID instead which will increase the cost base." (Professional Representative Body)

Similarly to CCGs and clinicians, another theme raised by this group focuses on the potential knock-on effects as a result of the changes, such as the prescription of more expensive alternatives

Industry

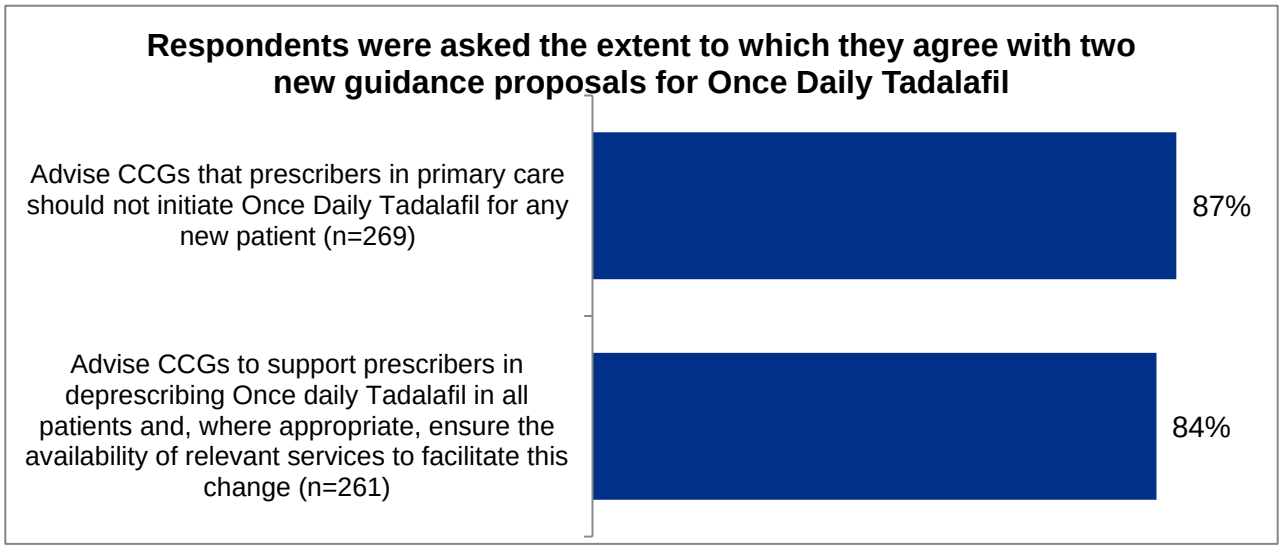
There was only one industry response and that highlights that the inclusion of a product in this category needs to be reviewed as PrescQIPP has incorrectly classified salicylate-containing topical products as Rubefacients; it should be classified as a topical NSAID and excluded from this consultation. It is not available to purchase over the counter unless the sale is supervised by a pharmacist.

4.16 Once Daily Tadalafil

Once Daily Tadalafil is used to treat erectile dysfunction in circumstances as set out in part XVIIIB of the Drug Tariff. Tadalafil is a phosphodiesterase-5-inhibitor and is available in strengths of 2.5mg, 5mg, 10mg and 20mg. 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'. The inclusion of Once Daily Tadalafil within this consultation is due to there not being enough evidence to routinely recommend once daily preparations in preference to 'when required' preparations.

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.

The chart below presents the extent to which all survey respondents agree with the two new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The key theme in favour of the proposal is that Tadalafil should not be funded by the NHS. The key theme not in favour of the proposal is that Tadalafil is an effective treatment and is required for a number of conditions.

Comments from participants at the patient and public engagement events largely focus on clarity around the provision of this treatment under schedule 2 and the effects of it not being provided (e.g. the cost to patients, equity of access). Cancer patients in particular are a group considered to be affected if this is removed.

"I feel that the removal of this prescribed medication, will have an effect on the quality of my life, and I would urge that it be kept available on prescription."

Members of public and family members

The key themes raised by this group include the availability of cheaper or more cost-effective alternatives, and that if a patient chooses to have this treatment, they should fund it themselves, possibly through private prescriptions.

CCGs

The key themes raised by CCGs are in agreement with the proposal, with comments focusing on how this treatment should be blacklisted and should not be funded by the NHS. There are also some comments highlighting the lack of proven evidence for the product's effectiveness.

"If the price of Once Daily Tadalafil could be reduced to the cost of On Demand Sildenafil following patent expiry then there would be no need to decommission Once Daily Tadalafil. The recommendations included in the consultation are concerned with treatment of BPH and ED, as per the product licence. However, locally, urology teams have tended to start Once Daily Tadalafil following surgery as 'penile rehabilitation' and in addition to on demand PDE5 inhibitors. If this continues to be accepted practice among urology specialists, it is unlikely that the results of the consultation will remove variation in prescribing. In addition, it would help CCGs reduce prescribing of Once-Daily Tadalafil to have some clearer guidance on the amount of support that the NHS overall considers appropriate for treatment of ED. Many GPs have interpreted previous guidance that the NHS would provide treatment for one episode of sexual activity per week, thus limiting prescriptions to four per month (with some even providing private prescriptions for quantities higher than this). Where patients have challenged the guidance and requested more on demand treatments, there is a point at which the monthly cost of on demand and daily treatment equals out. To implement this guidance, therefore, I think the NHS should be explicit in that it agrees to fund either up to a threshold monthly cost (beyond which the patient self funds) or a total number of episodes of sexual intercourse (beyond which the patient self funds)…"

Clinicians

The key theme raised in favour of the proposal focuses on the lack of evidence for the effectiveness of the treatment. However, some comment that this is an effective treatment.

Additionally, one clinician says that Tadalafil does not meet the criteria to be included in this consultation, commenting around the treatment's clinical effectiveness, cost effectiveness and NHS funding priorities.

CCGs, clinicians and other healthcare organisations think that when Once Daily Tadalafil comes off patent in November 2017 the cost of treatment will no longer be an issue as the generic price will be much lower.

Patient representative organisations, voluntary organisations and charities

Two respondents say that Tadalafil prescriptions are not an effective use of NHS resources and that it should not be funded by the NHS, whilst one argues that it is effective.

"Community Pharmacy Lancashire (CPL) supports these proposals, as these items are either dangerous or not the most effective treatment available. CPL believes that the national NHS prescribing blacklist should be used to restrict these products."

Other NHS organisations, provider organisations and professional bodies

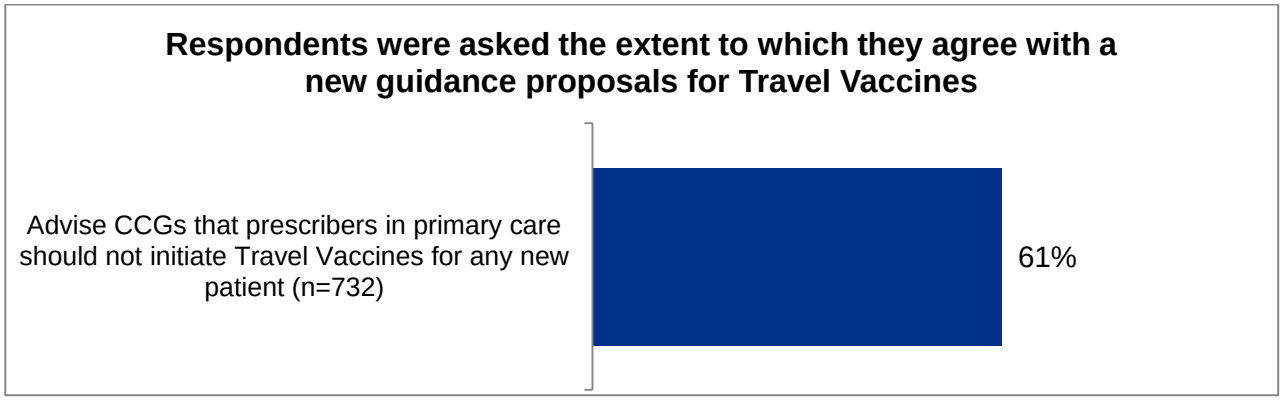
Respondents broadly agree that Tadalafil treatment is required for a number of conditions including benign prostatic hyperplasia and think NHS England should provide additional support for those suffering from erectile dysfunction.

NICE agrees with both recommendations and also notes that when exercising their judgement, health professionals are expected to take guidance fully into account, alongside the individual needs, preferences and values of their patients.

4.17 Travel Vaccines

Travel Vaccines are injections that are available to prevent illnesses abroad. Some Travel Vaccines are available on the NHS and others are not available on the NHS. Travel Vaccines not available on the NHS are sometimes inappropriately administered for the purposes of travel, due to them being available for prevention of illness in other circumstances. The inclusion of Travel Vaccines within this consultation is due to them being a low priority for NHS funding.

The chart below presents the extent to which all survey respondents agree with the new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Some comment that the cost of Travel Vaccines should be met by patients, whilst others state it should be funded by the NHS. Those against the proposal state that there is a cost saving overall for the NHS by not having to treat people returning with holiday diseases which could have been vaccinated against.

"The cost of a travel vaccination should be met by the patient. A patient who is able to afford travel should budget for vaccines as part of the cost."

Members of the public and family members

Responses from this cohort mirror those from patients. The key themes raised include: the cost of travel vaccines should be met by the patient; vaccines should remain on the NHS to provide valuable protection to the public's health; and vaccines provide a cost saving overall.

CCGs

CCG are generally in favour of the proposal, with participants commenting that patients should meet the cost of vaccines themselves. Some comments also request clear

guidance on use in exceptional circumstances (e.g. patients working abroad, doing voluntary work) and when vaccines would and would not be provided for free, especially for combination vaccines. An example was for Hepatitis B when patients are in a high risk group.

"If Travel Vaccine not provided; future cost in case of infection is projected to be high, treating disease."

"There needs to be clarity on the use of combined Hep A and B products as there is a lot of variation

nationally."

Clinicians

Clinicians agree with the proposal, with comments such as the cost should be met by patients being made. Some also suggest patients should be required to meet some of the cost or a proportion of cost for Travel Vaccines.

Some comment that the proposal would lead to increases in costs for the NHS because vaccines provide an overall cost saving and valuable public health protection.

"There is no reason why these should not be prescribed in primary care. They may prevent diseases that will be a burden on the NHS and there is intrinsically no difference between any of these and medication taken whilst travelling to prevent a pre-existing condition."

"Access to some of these vaccines is almost impossible in some areas, and primary care is the easiest place to access. If it was made simpler to charge and claim for these vaccines with a clear remit from Public Health, we could continue to provide Travel Vaccines appropriately."

Patient representative organisations, voluntary organisations and charities

The key themes amongst this group are similar to the comments provided by clinicians – the cost of Travel Vaccines should be met by the patient, they provide a cost saving overall and it is in the interest of public health.

Other NHS organisations, provider organisations and professional bodies

Some comment the cost should be met by the patient whilst others say it should remain on the NHS (e.g. the Royal Pharmaceutical Society). Those who argue the cost should be met by the NHS (e.g. Public Health England) highlight the extra costs of treating people who are not vaccinated, and the overall impact on public health and risk to public safety.

The British Medical Association neither agrees nor disagrees.

"These vaccines may be expensive for patients to obtain privately and adequate consideration needs to be given to the possible consequences and costs involved should appropriate vaccines not be given and a chronic disease is contracted. The burden of managing this disease will far outweigh any costs to the system of the initial vaccination programme."

Industry

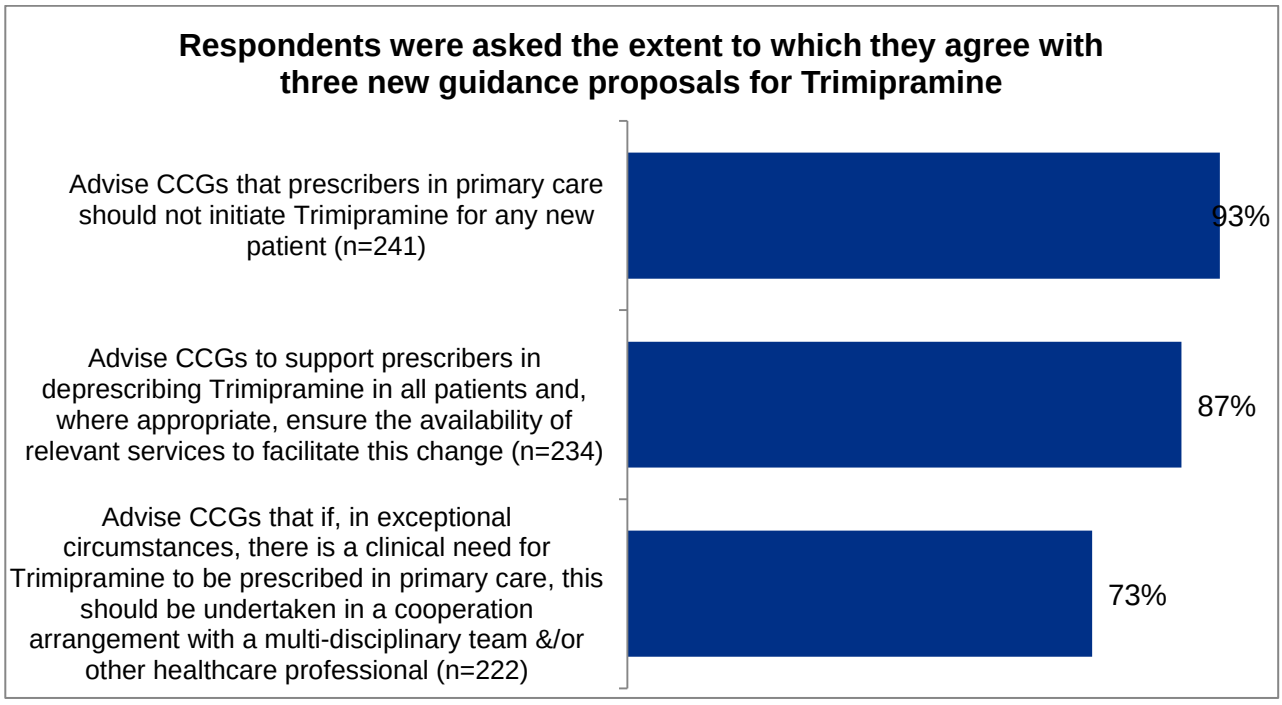
Companies who responded to the consultation voice their disagreement with the proposal.

"Preventative medicine is always cheaper than active treatment. A person infected with any of these diseases uses more resources and costs more to treat than the vaccines do."

4.18 Trimipramine

Trimipramine is an antidepressant (TCA) with the brand name Surmontil. The cost of Trimipramine is significantly more expensive than other antidepressants. NICE CG90: Depression in Adults recommends selective serotonin reuptake inhibitor (SSRI) antidepressants first line medicines are indicated as they have a more favourable risk to benefit ratio compared to TCA. However, if a TCA is required, there are more cost-effective TCAs available. Due to the significant cost associated with Trimipramine and the availability of alternative treatments, the group considered Trimipramine suitable for inclusion in the consultation.

The chart below presents the extent to which all survey respondents agree with the three new guidance proposals. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



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The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

This cohort comments there are a number of readily available, suitable alternatives but

consideration should be given to patients who are stable on Trimipramine. Some also request reassurance that the treatment can be re-prescribed if alternatives aren't effective.

"It is vital that GPs are given sufficient resources to spend time with patients discussing alternatives and managing the transition from Trimipramine to an alternative, with close monitoring and several follow-up appointments."

Members of the public and family members

Similarly to patients, this cohort also comments that here are a number of readily available, suitable alternatives but seeks reassurance that the treatment can be represcribed if alternatives are not effective. The comments from this group also show they are conscious there are cheaper or more cost-effective alternatives available.

"There are precious few, if any, good clinical reasons for still using tricyclic anti-depressants when more effective and safer alternatives have been available for decades."

CCGs

CCGs generally agree with the proposal and comment that the treatment should be blacklisted for all patients and that there are suitable alternatives available. Some are keen for prescribers to be given specialist guidance and education when changing treatments.

"Prescribers would need clear national advice on how to implement any changes and transition to alternative products, ensuring that both primary and secondary care are adopting the same approach."

Clinicians

Similarly to CCGs, clinicians generally agree with the proposal, commenting that the treatment should be blacklisted for all patients and that there are suitable alternatives available, including many that are cheaper and more cost-effective.

"Perfectly suitable alternatives that are much more cost effective. The cost of Trimipramine to the NHS is ridiculous."

Patient representative organisations, voluntary organisations and charities

Comments in favour of the proposal focus on the availability of suitable alternatives. Comments not in favour of the proposal cite the requirement to consider the effect on patients who have been taking this treatment for a long time and are stable on this treatment.

"…an expectation that any change to an alternative is completed via face-to-face consultation and agreement with the patient. This is because they may have been stable on this treatment for a long time and there is a risk of deterioration in their mental health wellbeing if the change is made without a full partnership between the patient and the prescriber."

Other NHS organisations, provider organisations and professional bodies

Comments from other organisational bodies convey their support for the proposals,

again highlighting suitable alternatives, whilst comments not in favour of the proposals include the consideration for patients who have been taking the treatment for a long time.

NICE agrees with the recommendations in line with guidance and individual patient needs, however the Royal College of Psychiatrists and Royal Pharmaceutical Society do not agree as they believe it is effective for some patients. The Royal Pharmaceutical Society argues that Trimipramine is a strong antidepressant with strong anti-anxiety effects, it does not interfere with normal sleep patterns and it is helpful in managing withdrawal from alcohol or narcotics.

5 Over the counter medication

In addition to the detailed recommendations made by the joint clinical working group for the list of 18 products, another area of NHS prescribing that has been suggested for consideration regards those products which can also be purchased over the counter.

5.1 Views and relevant evidence that NHS England should consider

Respondents were asked to provide their views and relevant evidence that NHS England should consider when developing proposals to potentially restrict items that are available over the counter. In total 5,543 respondents provided feedback on the questions in this section.

Top themes

From the comments, the three main themes overall from all respondent types regarding the proposal to stop prescribing medicines available over the counter are:

1) Treatments available over the counter should not be prescribed
2) Over the counter medicines should not be prescribed unless there is a specific need from the individual
3) Restriction of over the counter medicines just because of the cost to the NHS is unfair on vulnerable groups.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

Patients also comment that readily available treatments that are cheap to buy over the counter should be considered for prescribing restriction.

"I think there needs to be clear guidance when items can be prescribed to avoid any mis-interpretations by prescribers or patients, items should be restricted as we do not have the funds to support self-care and items are available much cheaper than it would cost NHS."

Members of the public and family members

This group also comment that readily available treatments that are cheap to buy over the counter should be considered for prescribing restriction and treatments with evidence of clinical effectiveness should not be restricted just because of the cost to the NHS.

"Agree in general, but for medicines that are effective, there should be prescription for those who cannot afford to buy them – those on free prescriptions linked to being on benefits (but not pensioners who are not receiving benefits other than the state pension)."

CCGs

Other themes raised by CCGs include the requirement for clear guidance and education from NHS England to implement this effectively and the effect this proposal will have on patients who require a large amount of prescribed over the counter medication.

"Items which are readily and inexpensively available should be recommended to be purchased by patients if for short-term conditions or covered by the over the counter licence."

Clinicians

The additional key themes emerging from clinicians are that considerations must be made for those who require a large supply of over the counter medication (e.g. to manage a chronic/long-term condition) and those items that are readily available over the counter cheaply should be considered for prescribing restriction.

"Happy as long as people needing long-term treatment can still get on prescription e.g. paracetamol, where there is a restriction on amount that can be sold."

Patient representative organisations, voluntary organisations and charities

This group also comments that when making decisions, consideration must be made for those with long-term conditions who require a large supply of over the counter medicine, and that the deprescription of these items could result in patient compliance and clinician monitoring issues. Some also comment that treatments that are available over the counter cheaply should be considered for prescribing restriction.

"Some patients with a long-term condition, taking aspirin as an example for heart conditions, may not continue their treatment if it is no longer prescribed. Surely the doctor is best to make the decision and sadly many prescribe for things that the patient should not even present for. They must …ensure both a reduction in unnecessary prescribing and consultations."

Other NHS organisations, provider organisations and professional bodies

Organisational bodies cite similar themes – considerations have to be made for those with long-term conditions who require a large supply of over the counter medication and items that are readily available at a low cost should not be prescribed. This cohort also comments that there should be greater utilisation of community pharmacies in aiding patients to source treatments needed.

Industry

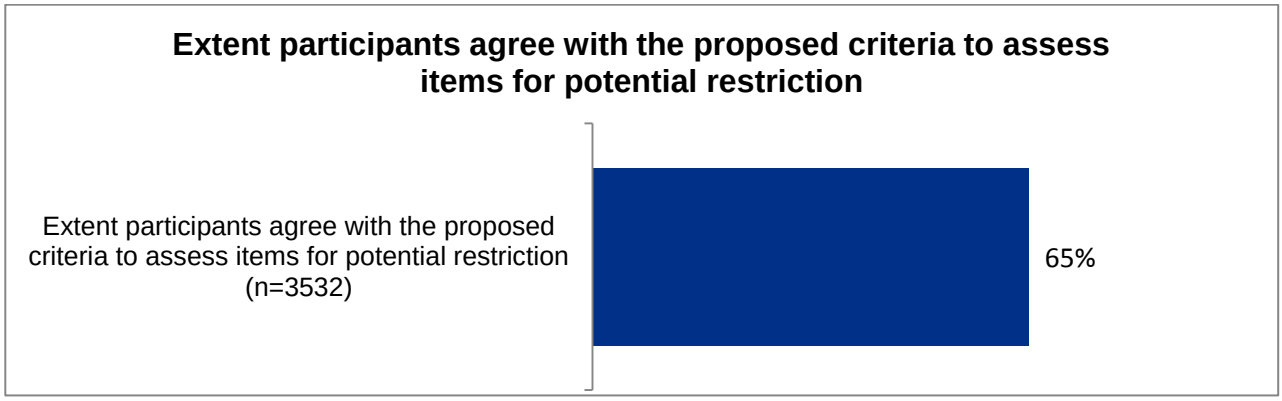
Industry bodies also comment healthcare professionals should be able to advise on

whether these treatments are necessary – the deprescription of these items could result in patient compliance and clinician monitoring issues and the impact on healthcare professionals as a result of these changes should also be considered.

5.2 Agreement with proposed criteria

Respondents were asked to identify the extent to which they agree with the proposed criteria to assess items for potential restriction and identify products, which are either clinically ineffective or available over the counter, for prioritising for early review.

The chart below presents the extent to which all survey respondents agree with the proposed criteria to assess items for potential restriction. For a breakdown of the extent to which survey respondents agree by type, please see the annex.



N.B. Respondents were asked whether they 'agree', 'disagree', 'unsure' or 'don't know' to the proposal questions. The bars show percentages calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure. A full breakdown by respondent type can be found in the annex.

The section below presents the themes raised in written comments by respondents of each type. The comments have come from the survey, correspondence, webinars and meetings.

Patients

The common themes discussed amongst this cohort relate to concerns and queries around the evidence consulted when informing the proposal, that the proposal goes against patients' freedom of choice and that items not available over the counter should not be removed.

"Freedom of choice and for doctors to be allowed and be encouraged to exercise their judgment and experiment outside the highly restrictive tick-box guidelines."

Members of public and family members

Common themes mentioned by this cohort include: concerns or questions around the evidence consulted when informing the proposal; decisions should be based on more than just the cost of the treatment to the NHS; the proposal goes against patients' freedom of choice; and assessments must be made on the requirements of individual patients and their needs.

CCGs

The key themes raised by this cohort include: concerns some may not want to pay or be

able to afford the treatment; the restrictions on the quantities that can be purchased over the counter should be reconsidered; the requirement for clearer guidance; and that consideration should be given to the impact on vulnerable groups.

"Often people request a prescription as it is cheaper than purchasing products if they get free prescriptions. We should consider a small token fee for all prescriptions. Entitlement to free prescriptions should be reviewed e.g. wealthy elderly, working retired, and people with endocrine disorders getting all prescriptions free."

Clinicians

The common themes discussed amongst this cohort relate to concerns around the evidence used. Clinicians also voiced concerns around patient freedom of choice and the belief that these decisions should be made on more than the cost of the treatment to the NHS.

Patient representative organisations, voluntary organisations and charities

Comments from this group focus on the consultation process and guidance, including that: clearer guidance and education is required to implement this effectively; the effectiveness of treatments should be considered by speaking to users of the treatments; and there are concerns around the evidence used to formulate the proposal. There are also comments relating to the requirement to carry out assessments based on patient needs, the impact on vulnerable groups and concerns that some patients may not be able to afford treatments.

"I agree that the NHS needs to save money but the whole consultation and any resulting alteration of the guidelines needs to be done fairly, taking each patient's needs into consideration." (Voluntary organisation)

Other NHS organisations, provider organisations and professional bodies

Common themes amongst this group include concerns around the evidence used and that some cohorts may not want or be able to afford to pay for these treatments over the counter. Other themes mentioned include the need to consider the impact on vulnerable groups and quality of life overall. There are concerns around the possibility of unintended consequences as a result of the changes, e.g. greater pressure on healthcare professionals.

Some comments also mention the requirement to take into consideration the impact on those with long-term conditions and those with self-limiting ailments, as well as the need for clearer guidance around the proposal.

Industry

Industry bodies comment that more than cost to the NHS should be considered when making these decisions and the effectiveness of treatments should be evaluated by speaking to those who use them. Other points raised include: the possible impacts on healthcare professionals as a result of the changes; concerns some may not be able to pay for these treatments; and the belief that there should be a greater emphasis on self-care and patient empowerment.

Most commonly mentioned over the counter products that should be prioritised for early review	
Treatment	**No. of mentions**
Paracetamol	280
Homeopathy	225
Ibuprofen	110
Herbal treatments	89
Cough mixtures/medicines	79
Antihistamines	75
Cold remedies	57
Ready-made gluten free items	49
Analgesia products	47
Vitamins	46
Skin Emollients	42
Sun cream/sun tan lotions	38
All over the counter medicines	36
Painkillers	34
Aspirin	33
NSAID gels/creams	32
Gastric anti-acid products	32
Moisturisers/treatments for dry skin	30
Hay fever treatments	29
Base	*1,345*

6 Feedback on our proposals to update guidance

This section presents respondents' views and opinions on the proposed process for identification of items for possible addition or removal from the guidance.

Consultation respondents were asked to provide feedback on how they thought guidance should be updated and revised in the future. Respondents were asked how they felt about the proposed process for identification of items for possible addition to the guidance or possible removal from the guidance.

Almost all respondents to the consultation commented (5,353). There was an almost equal split between those who agreed with the proposed process for identification (32% and those who disagreed (37%). Only 15% neither agreed nor disagreed and 16% were unsure.

Patients

Patients are concerned about the impact that the removal of treatments will have on some patients. They say that the effectiveness of treatments should be gauged by speaking to those who use them. Some are concerned about what evidence was used when informing the proposal, whilst others suggest negotiating the current pricing from sole provider of this treatment to the UK because the treatments is cheaper in Europe. Patients also feel that the proposal goes against a patient's freedom to choose their treatment.

Members of the public and family

This group raises the same points as the patients. They also say that proposals should be based on cost, efficacy and whether the alternatives are of equal benefit and cost effectiveness.

CCGs

CCGs agree that the proposal makes better use of limited NHS resources but suggest further amendments. They suggest that there should be a review and treatment change where necessary if the treatment has new or safer alternatives.

"Vast amounts of money are being used from the NHS pot by people who are prescribed these less appropriate treatments. CCGs at the moment have work in place to reduce this cost, but to remove the option would ensure that CCGs could move their work in medicines management forward, whilst using the NHS purse appropriately."

Clinicians

Clinicians raise similar points to the patients. They express concerns over evidence consulted, and that the proposals go against a patient's freedom to choose their treatment. They suggest further amendments to the proposal, better use of limited NHS resources and consideration of the effectiveness of treatments by speaking to those using them.

"It depends how it actually works in practice. It needs to have detailed feedback from patients and clinicians and this should be actively sought rather than waiting for interested parties to contact the CCG."

"There is no point in wasting money on items that have been shown not to work. It takes funds away from useful treatments. It gives useless therapies a veneer of respectability."

Patient representative organisations, voluntary organisations and charities

This cohort raises concerns around the evidence consulted to inform the proposal, and the impact on a patient's freedom to choose their treatment. Further amendments are suggested.

Professional representative bodies and other healthcare organisations

These groups mention the same points raised by the other stakeholder groups. They also state that a more robust system for adding and removing treatments with equal representation from all stakeholders is needed.

"The process does not seem robust! Instead it seems deliberately otherwise, to take acceptance of a very robust process carried out for non-contentious items to then carry out a 'light' version without good consultation on more contentious medicines."
(Professional Representative Body)

Industry

Respondents from the industry are concerned about the evidence consulted when informing the proposal, but they agree that the proposal makes better use of limited NHS resources. They add that a robust system is needed for adding and removing treatments and that this should have equal representation from all stakeholders.

7 Annex

The breakdown of responses to the closed questions for each of the products is presented in this annex. The first data row shows the percentages presented in the charts in the product sections. The subsequent rows show how the different respondent types answered these questions (note – some respondents did not specify a type and are therefore included under 'all responses' but not within the subcategories below)

Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** has been calculated as a proportion of those who 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and 'unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Co-proxamol

Respondents were asked the extent to which they agree with three new guidance proposals for Co-proxamol. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Co-proxamol for any new patient		Q2. To support prescribers in deprescribing Co-proxamol in all patients		Q3. That in exceptional circumstances if there is a clinical need for Co-proxamol to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**85%**	**1234**	**85%**	**1213**	**74%**	**1226**
All responses	71%	1,488	70%	1,480	61%	1,494
CCG	98%	120	95%	118	43%	118
Other healthcare organisation	98%	43	88%	43	67%	43
Clinician	90%	353	85%	352	64%	354
Other	87%	70	80%	69	61%	72
Professional representative body	74%	23	68%	22	55%	22
Industry	67%	3	67%	3	67%	3
Members of the public	66%	319	67%	318	59%	318
Patient representative / voluntary / charity organisation	53%	64	62%	65	64%	73
Patient	52%	485	53%	483	491	63%

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Dosulepin

Respondents were asked the extent to which they agree with three new guidance proposals for Dosulepin. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Dosulepin for any new patient		Q2. To support prescribers in deprescribing Dosulepin in all patients		Q3. That if, in exceptional circumstances, if there is a clinical need for Dosulepin to be prescribed in primary care, this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**84%**	**302**	**75%**	**289**	**72%**	**280**
All respondent responses	80%	316	69%	315	64%	315
CCG	99%	89	90%	88	68%	88
Clinician	74%	103	63%	103	63%	104
Other	84%	25	64%	25	64%	25
Professional representative body	100%	7	86%	7	29%	7
Industry	0%	1	0%	1	0%	1
Members of the public	76%	29	69%	29	62%	29
Patient representative / voluntary / charity organisation	75%	4	25%	4	25%	4
Patient	53%	43	42%	43	71%	42
Other healthcare organisation	93%	14	71%	1	57%	14

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Prolonged-release Doxazosin

Respondents were asked the extent to which they agree with three new guidance proposals for Prolonged-release Doxazosin. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Prolonged-release Doxazosin for any new patient		Q2. To support prescribers in deprescribing Prolonged-release Doxazosin in all patients		Q3. That in exceptional circumstances if there is a clinical need for Prolonged-release Doxazosin to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**87%**	**254**	**83%**	**255**	**59%**	**245**
All respondent responses	80%	277	77%	276	53%	273
CCG	95%	87	93%	86	51%	85
Clinician	83%	86	81%	86	56%	84
Other	100%	9	82%	17	53%	17
Professional representative body	78%	9	78%	9	33%	9
Industry	0%	1	0%	1	0%	1
Members of the public	61%	23	57%	23	57%	23
Patient representative / voluntary / charity organisation	50%	4	50%	4	75%	4
Patient	53%	40	45%	40	48%	40

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Immediate-release Fentanyl

Respondents were asked the extent to which they agree with three new guidance proposals for Immediate-release Fentanyl. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Immediate-release Fentanyl for any new patient		Q2. To support prescribers in deprescribing Immediate-release Fentanyl in all patients		Q3. That in exceptional circumstances if there is a clinical need for Immediate-release Fentanyl to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**65%**	**387**	**59%**	**375**	**76%**	**380**
All responses	60%	425	52%	425	68%	422
CCG	86%	90	80%	89	76%	88
Other healthcare organisation	75%	16	69%	16	75%	16
Clinician	67%	147	53%	148	76%	148
Other	55%	22	41%	22	55%	22
Professional representative body	50%	10	50%	10	67%	79
Industry	11%	9	11%	9	22%	9
Members of the public	35%	60	33%	60	50%	60
Patient representative / voluntary / charity organisation	43%	7	29%	7	71%	7
Patient	35%	62	37%	62	67%	61

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Glucosamine and Chondroitin

Respondents were asked the extent to which they agree with two new guidance proposals for Glucosamine and Chondroitin. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Glucosamine and Chondroitin for any new patient		Q2. To support prescribers in deprescribing Glucosamine and Chondroitin in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**73%**	**457**	**72%**	**458**
All respondent responses	71%	471	70%	473
CCG	98%	92	95%	91
Other healthcare organisation	92%	13	85%	13
Clinician	88%	112	81%	112
Other	87%	23	83%	24
Professional representative body	69%	13	69%	13
Industry	-	0	-	0
Members of the public	56%	85	58%	85
Patient representative / voluntary / charity organisation	57%	7	57%	8
Patient	41%	125	46%	127

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Herbal Treatments

Respondents were asked the extent to which they agree with three new guidance proposals for Herbal Treatments. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Herbal Treatments for any new patient		Q2. To support prescribers in deprescribing Herbal Treatments in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**46%**	**1349**	**52%**	**1321**
All responses	45%	1,367	51%	1,364
CCG	98%	92	93%	91
Clinician	66%	176	65%	175
Other	62%	53	58%	53
Professional representative body	44%	16	50%	16
Industry	33%	6	33%	6
Members of the public	48%	439	53%	438
Patient representative / voluntary / charity organisation	32%	25	40%	25
Patient	24%	536	36%	536

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Homeopathy

Respondents were asked the extent to which they agree with three new guidance proposals for Homeopathy. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Homeopathy for any new patient		Q2. To support prescribers in deprescribing Homeopathy in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**46%**	**2402**	**52%**	**2361**
All responses	46%	2,421	50%	2,412
CCG	94%	90	93%	89
Clinician	56%	312	54%	312
Other	46%	100	49%	97
Professional representative body	50%	18	56%	18
Other healthcare organisation	53%	30	60%	30
Industry	60%	5	80%	5
Members of the public	55%	946	57%	946
Patient representative / voluntary / charity organisation	50%	18	36%	33
Patient	27%	875	37%	872

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Lidocaine Plasters

Respondents were asked the extent to which they agree with three new guidance proposals for Lidocaine Plasters. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Lidocaine Plasters for any new patient		Q2. To support prescribers in deprescribing Lidocaine Plasters in all patients		Q3. That in exceptional circumstances if there is a clinical need for Lidocaine Plasters to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**59%**	**484**	**58%**	**472**	**71%**	**464**
All responses	54%	527	52%	526	62%	526
CCG	86%	95	82%	94	61%	94
Clinician	54%	217	47%	216	66%	217
Other	79%	28	57%	28	61%	28
Professional representative body	60%	10	60%	10	50%	10
Industry	50%	2	50%	2	0%	2
Members of the public	46%	41	56%	41	54%	41
Patient representative / voluntary / charity organisation	29%	7	29%	7	71%	7
Patient	21%	113	31%	114	61%	113

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Liothyronine

Respondents were asked the extent to which they agree with three new guidance proposals for Liothyronine. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Liothyronine for any new patient		Q2. To support prescribers in deprescribing Liothyronine in all patients		Q3. That in exceptional circumstances if there is a clinical need for Liothyronine to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**16%**	**1646**	**28%**	**1640**	**51%**	**1420**
All responses	16%	1,691	27%	1,687	43%	1,687
CCG	94%	95	90%	94	61%	94
Clinician	75%	117	69%	117	66%	116
Other healthcare organisation	100%	11	82%	11	64%	11
Other	63%	24	50%	24	57%	23
Professional representative body	73%	11	70%	10	64%	11
Industry	40%	5	0%	5	60%	5
Members of the public	9%	227	19%	226	39%	228
Patient representative / voluntary / charity organisation	42%	12	42%	12	58%	12
Patient	3%	1,184	18%	1,183	39%	1,182

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Lutein and Antioxidants

Respondents were asked the extent to which they agree with two new guidance proposals for Lutein and Antioxidants. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Lutein and Antioxidants for any new patient.		Q2. To support prescribers in deprescribing Lutein and Antioxidants in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	
	No. agreeing with proposal	No. answering question	No. agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**74%**	**319**	**73%**	**318**
All respondent responses	71%	332	70%	332
CCG	97%	91	94%	90
Clinician	90%	79	85%	79
Other	70%	20	60%	20
Professional representative body	50%	12	42%	12
Industry	0%	1	0%	1
Members of the public	55%	40	54%	41
Patient representative / voluntary / charity organisation	38%	8	38%	8
Patient	30%	69	42%	69
Other healthcare organisation	100%	9	89%	9

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Omega-3 fatty acid compounds

Respondents were asked the extent to which they agree with two new guidance proposals for Omega-3 fatty acid compounds. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Omega-3 fatty acid compounds for any new patient		Q2. To support prescribers in deprescribing Omega-3 fatty acid compounds in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**69%**	**421**	**72%**	**418**
All responses	67%	433	68%	438
CCG	97%	86	90%	87
Other healthcare organisation	92%	12	83%	12
Clinician	85%	86	84%	87
Other	70%	23	63%	24
Professional representative body	67%	9	67%	9
Industry	100%	1	100%	1
Members of the public	52%	93	56%	93
Patient representative / voluntary / charity organisation	67%	6	67%	6
Patient	41%	115	50%	117

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Oxycodone and Naloxone Combination Product

Respondents were asked the extent to which they agree with three new guidance proposals for Oxycodone and Naloxone Combination Product. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Oxycodone and Naloxone Combination Product for any new patient		Q2. To support prescribers in deprescribing Oxycodone and Naloxone Combination Product in all patients		Q3. That in exceptional circumstances if there is a clinical need for Oxycodone and Naloxone Combination Product to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**85%**	**279**	**86%**	**270**	**72%**	**260**
All respondent responses	81%	294	79%	292	64%	291
CCG	98%	87	97%	86	59%	86
Clinician	84%	102	78%	100	76%	99
Other	81%	16	69%	16	50%	16
Professional representative body	75%	8	88%	8	63%	8
Industry	N/A	N/A	N/A	N/A	N/A	N/A
Members of the public	71%	24	71%	24	67%	24
Patient representative / voluntary / charity organisation	25%	4	50%	4	25%	4
Patient	49%	41	59%	41	54%	41

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Paracetamol and Tramadol Combination Product

Respondents were asked the extent to which they agree with two new guidance proposals for Paracetamol and Tramadol Combination Product. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Paracetamol and Tramadol Combination Product for any new patient		Q2. To support prescribers in deprescribing Paracetamol and Tramadol Combination Product in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**77%**	**426**	**77%**	**421**
All respondent responses	73%	447	73%	448
CCG	98%	86	97%	86
Clinician	87%	103	82%	103
Other	86%	21	81%	21
Professional representative body	78%	9	78%	9
Industry	50%	2	50%	2
Members of the public	67%	60	67%	61
Patient representative / voluntary / charity organisation	82%	11	73%	11
Patient	45%	139	51%	139

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Perindopril Arginine

Respondents were asked the extent to which they agree with three new guidance proposals for Perindopril Arginine. They were to advise CCGs:

Respondent type	Q1. That prescribers in primary care **should not** initiate Perindopril Arginine for any new patient		Q2. To support prescribers in deprescribing Perindopril Arginine in all patients	
	No. agreeing with proposal	No. answering question	No. agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**92%**	**237**	**90%**	**231**
All respondent responses	88%	246	85%	244
CCG	97%	86	95%	84
Clinician	92%	65	88%	65
Other	94%	17	88%	17
Professional representative body	88%	8	88%	8
Industry	0%	1	0%	1
Members of the public	75%	24	67%	24
Patient representative / voluntary / charity organisation	100%	2	100%	2
Patient	63%	32	63%	32

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Rubefacients

Respondents were asked the extent to which they agree with two new guidance proposals for Rubefacients. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Rubefacients for any new patient		Q2. To support prescribers in deprescribing Rubefacients in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**76%**	**288**	**78%**	**285**
All respondent responses	76%	306	73%	305
CCG	92%	86	91%	85
Other healthcare organisation	85%	13	92%	13
Clinician	60%	99	61%	99
Other	64%	22	73%	22
Professional representative body	75%	8	50%	8
Industry	50%	2	50%	2
Members of the public	82%	34	82%	34
Patient representative / voluntary / charity organisation	100%	2	100%	2
Patient	46%	39	54%	39

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Once Daily Tadalafil

Respondents were asked the extent to which they agree with two new guidance proposals for Once Daily Tadalafil. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Once Daily Tadalafil for any new patient		Q2. To support prescribers in deprescribing Once Daily Tadalafil in all patients	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**87%**	**269**	**84%**	**261**
All respondent responses	83%	283	77%	282
CCG	94%	87	92%	86
Clinician	80%	89	72%	89
Other	95%	19	89%	19
Professional representative body	63%	8	63%	8
Industry	50%	2	50%	2
Members of the public	79%	28	64%	28
Patient representative / voluntary / charity organisation	100%	2	50%	2
Patient	57%	35	60%	35

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Travel Vaccines

Respondents were asked the extent to which they agree with three new guidance proposals for Travel Vaccines. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Travel Vaccines for any new patient	
	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**61%**	**732**
All respondent responses	54%	815
CCG	88%	92
Other healthcare organisation	63%	19
Clinician	67%	161
Other	77%	35
Professional representative body	50%	18
Industry	14%	7
Members of the public	45%	189
Patient representative / voluntary / charity organisation	27%	26
Patient	43%	264

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Trimipramine

Respondents were asked the extent to which they agree with three new guidance proposals for Trimipramine. They were, to advise CCGs:

Respondent type	Q1. That prescribers in primary care should not initiate Trimipramine for any new patient		Q2. To support prescribers in deprescribing Trimipramine in all patients		Q3. That in exceptional circumstances if there is a clinical need for Trimipramine to be prescribed in primary care this should be undertaken in cooperation arrangement with a multidisciplinary team and/or other healthcare professional	
	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**93%**	**241**	**87%**	**234**	**73%**	**222**
All respondent responses	87%	258	80%	256	64%	255
CCG	97%	87	94%	86	64%	86
Clinician	94%	68	88%	68	75%	67
Other	100%	20	73%	11	58%	19
Professional representative body	100%	7	67%	3	57%	7
Industry	0%	1	0%	1	0%	1
Members of the public	68%	25	63%	24	52%	25
Patient representative / voluntary / charity organisation	67%	3	67%	3	67%	7
Patient	60%	35	51%	35	54%	35

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.

Over the Counter medicines

Extent participants agree with the proposed criteria to assess items for potential restriction

Respondent type	Q1. Do you agree with our proposed criteria to assess items for potential restriction?	
	% agreeing with proposal	No. answering question
Respondents who agree (excl. 'don't know' and 'unsure')	**65%**	**3532**
All responses	44%	5,248
CCG	93%	129
Other healthcare organisation	71%	65
Clinician	66%	731
Other	61%	171
Professional representative body	39%	49
Industry	18%	28
Members of the public	50%	1,412
Patient representative / voluntary / charity organisation	56%	118
Patient	29%	2,518

N.B. Respondents were asked whether they 'agree', 'disagree', 'neither agree nor disagree' or 'unsure' to the proposal questions. Row **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure') has been calculated as a proportion of those who** 'agree' /'disagree' and excludes those who said 'neither agree nor disagree' and unsure'. For all rows after **Respondents who agree (excl. 'neither agree nor disagree' and 'unsure')** the percentage in agreement has been calculated as a proportion of those who stated they 'agreed', 'disagreed', 'neither agree nor disagree' and 'unsure'.