HOMEOPATHY RESEARCH INSTITUTE

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

Homeopathy Research Institute submission to public consultation by NHS England

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HRI is an innovative international charity created to address the need for high quality scientific research in homeopathy.

N.B. The following written submission contains answers to those questions which relate to homeopathy which HRI has responded to via the online submission form (i.e. Sections 3 and 4). They are provided below in reverse order for ease of following the arguments presented.

Section 4: Proposals for CCG commissioning guidance

Please select which items you would like to share your views on (please select)?

- Homeopathy

Homeopathy
Do you agree with the proposed recommendations for homeopathy?

- Disagree

If needed, please provide further information

NHS England proposes to advise clinical commissioning groups,

- 'that prescribers in primary care should not initiate homeopathic items for any new patient' and
- 'to support prescribers in deprescribing homeopathic items in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.'[1]

This proposal to cease the prescription of homeopathic medicines within the NHS to both existing patients and new patients cannot go ahead as it has not been justified in regard to economics, ethics, scientific evidence or basic common sense.

The situation is simple. At present, homeopathy is being provided on the NHS to patients who want it, need it and report clinical benefit from it, at the near-negligible cost of **£92,412** per year (0.001% of the total **£9.2 billion** spent on prescriptions in primary care).

To put this figure in context, most of the 18 'items' being considered within this proposal are **single pharmaceutical drugs, each costing the NHS millions of pounds per year** (see Table 1

below) e.g. a paracetamol and tramadol combination painkiller costing c£2 million per year and a single thyroid drug, Liothyronine, costing c£35 million per year.

By contrast, the **combined cost of all homeopathic prescriptions is** c**£92,000** per year.

Table 1. Cost per annum of items under consideration (data extracted from 'Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs' (hereafter the Consultation Document, CD) p.9-24[1]

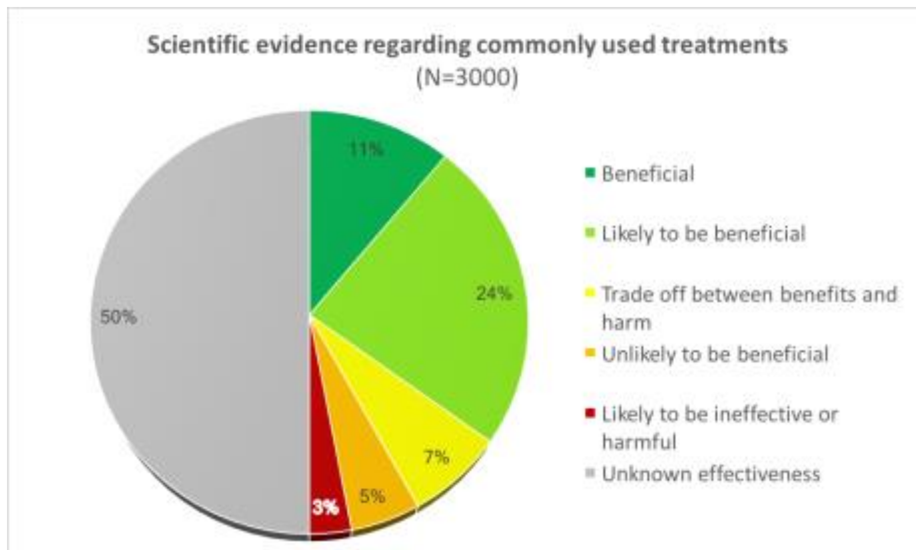
Medicine	Details	Cost per year
Liothyronine (T3)	Single drug	£34,802,312
Trimipramine	Single drug	£19,835,783
Lidocaine plasters	Single item	£19,295,030
Tadalafil once daily	Single drug	£11,474,221
Fentanyl	Single drug	£10,952,130
Co-proxamol	Single drug	£9,002,824
Doxazosin	Single drug	£7,769,931
Omega-3 fatty acid compounds	Single supplement	£6,317,927
Oxycodone &Naloxone combination	Single drug	£5,062,928
Travel vaccines	Group of various vaccines	£4,540,351
Rubefacients	Single drug	£4,301,527
Dosulepin	Single drug	£2,651,544
Paracetamol & Tramadol combination	Single drug	£1,980,000
Lutein and antioxidants	Group of various supplements	£1,500,000
Perindopril Arginine	Single drug	£529,403
Glucosamine and Chondroitin	Two different nutraceuticals	£444,535
Herbal treatments	All herbal medicines	£100,009
Homeopathy	**All homeopathic medicines**	**£92,412**

This stark contrast raises questions as to why homeopathic medicines have been included in this proposal at all. NHS England (NHS E) claim that it is because there is a 'lack of robust evidence of clinical effectiveness'. However, NHS E will be fully aware of the analysis by the British Medical Journal's Clinical Evidence research group[2] which shows that **1,500 treatments currently provided on the NHS** (50% of those analysed) **are of unknown clinical effectiveness** (see Fig 1).

NHS E therefore needs to explain why, out of these 1,500 treatments they could have included in this proposal, they chose homeopathic medicines which are so inexpensive.

NHS E's choice to ban homeopathic medicines is even harder to understand when the available data clearly and consistently demonstrates that patients report clinical benefits from these prescriptions.

Fig. 1. Scientific evidence regarding 3,000 commonly used treatments[2]



Four published research studies have tracked the outcome of patients being treated at NHS homeopathic hospitals and clinics in Bristol, Glasgow, Liverpool, London and Tunbridge Wells (see https://www.hri-research.org/resources/essentialevidence/observational-studies).[3,4,5,6]

The largest of these observational studies[3] analysed over **6,500 consecutive patients** treated at Bristol Homeopathic Hospital, including over 23,000 attendances; **70% of follow-up patients reported 'improved health', with 50% reporting 'major improvement'**. The largest improvements were seen in children with eczema or asthma, and adults treated for inflammatory bowel disease, irritable bowel syndrome, menopausal problems and migraine.

Bearing in mind that patients are usually referred for homeopathic treatment because conventional medicine has failed to provide sufficient clinical benefit, or because conventional medicine is contraindicated, these results demonstrate that homeopathic prescriptions provide excellent 'value for money'.

Any decision taken to remove such clinically beneficial, low cost prescriptions would have to be fully justified to the patients who currently use them, to the doctors who prescribe them and the general public who may wish to use these medicines in future.

The nature of the required justification is straight forward – NHS E must demonstrate that a decision to remove homeopathic medicines is ethically sound, economically sound and legal.

- It is only ethical to remove homeopathic medicines if an alternative treatment option is provided which gives similar or superior clinical benefits.
- It is only economically justified to remove homeopathic medicines if the replacement treatment options cost the same or less than homeopathic prescriptions.
- It is only legal if NHS E's actions comply with the Equality Act 2010 (see below).

In order to go ahead with this proposal, it would therefore be necessary for NHS E to provide the public with the following information:

1. Specific details of what alternative treatments will provided in place of homeopathy, especially in cases where conventional medicine has already failed or is contraindicated. N.B. NHS E has stated that 'Guidance on suitable alternatives and the indication for use will be provided' (CD p.31), yet they have failed to provide this information.

2. Evidence that the replacement treatments will lead to a minimum clinical outcome of "improved health" in 70% of patients and "major improvement" in 50% of patients[3]

3. Evidence that the replacement prescriptions will cost less than £92,412 per annum. N.B. NHS E has stated that, when considering 'unintended potential consequences' of this proposal 'alternatives may need to be considered including their cost impact' (CD p.31), yet they have failed to provide this information.

4. Evidence that removing homeopathic medicines will not put NHS E in breach of the Equality Act 2010 (a risk identified in Appendix 3, CD p.33). This requires an assessment of patients currently using homeopathy in terms of 'age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage and civil partnership, pregnancy and maternity'.

If this information cannot be provided in its entirety, the proposal to remove homeopathic medicines from the NHS cannot proceed.

NHS E's scientific justification for removing homeopathic medicines is invalid

The joint working group behind this proposal identified homeopathic medicines as being suitable for inclusion on the list of items which should not be routinely prescribed in primary care on the basis that they are, "Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns" (CD, p.14) [our use of underline].

At the NHS Clinical Commissioners' public consultation meeting in London (5 September 2017), the Chair, Neil Churchill, stated that decisions being taken within this consultation, *"Can't be based on emotive decision-making. They need to be based on firm data."*

HRI could not agree more. Any member of the public would expect that the working group's decisions would have been based on 'firm data', yet the only evidence provided to back up this decision is a single non-peer reviewed, non-scientific report written by a handful of politicians – the 2010 report by the House of Commons Science and Technology Committee 2010 (hereafter referred to as the Evidence Check 2 report, EC2)[7].

The multiple serious procedural and scientific failures associated with the EC2 report are outlined on the following page of the HRI website: https://www.hri-research.org/resources/homeopathy-the-debate/uk-select-committee-report/.

Collectively, these flaws make the EC2 report 'an unreliable source of information on homeopathy'[8] and explain why only 3 MPs voted in favour of the report and 70 MPs signed a statement of protest against it.[9]

Another pertinent issue is the irrelevance of the information covered by the EC2 report. The 'evidence check' only considered **efficacy** of homeopathy, specifically systematic reviews of randomised controlled trials. **All evidence on clinical effectiveness was excluded**, including pragmatic randomised controlled trials and observational studies.

How is it therefore possible for the joint working group to pass judgement on the **clinical effectiveness** of homeopathic medicines when they haven't looked at any clinical effectiveness data at all, let alone make the definitive pronouncement that they are "Products of low clinical effectiveness"?

Considering the emphasis put on the concept of evidence-based medicine by NHS England decision-makers, this is nothing less than appalling.

NHS E have also failed to cite the most up to date, relevant and robust data available on homeopathic medicines.

Homeopathic treatment provided on the NHS mostly takes the form of **individualised homeopathic treatment** (IHT) which involves an in-depth consultation, followed by a bespoke prescription based on the specific symptoms of the patient. IHT is generally considered to be the 'gold standard' of homeopathic treatment and in research terms is 'usual care'. This is not to be confused with **non-individualised homeopathy** where a single product, containing multiple homeopathic medicines, is prescribed to all patients based on clinical diagnosis alone e.g. over-the-counter homeopathic medicines.

The most recent and robust systematic review assessing efficacy of homeopathic medicines (Mathie et al, 2014) found that, **when prescribed during individualised treatment, homeopathic medicines are 1.5 to 2.0 times more likely to have a beneficial effect than placebo**[10].

It should be noted that as **the EC2 report** cited by NHS E in this consultation was written in 2010 and only considered data published up until 2005, it **does not include this more recent study** which provides 'firm data' demonstrating efficacy of homeopathic prescriptions.

Having made NHS E aware of the unreliability and lack of relevance of the EC2 report, as well as sources of directly relevant clinical research on homeopathy, if the proposal to remove homeopathic medicines *does* go ahead, NHS E will need to explain the following:

1. How the EC2 report qualifies as 'firm data',
2. The reasons for citing the EC2 report rather than directly relevant peer reviewed scientific literature, and
3. An example of a past-precedent for removal of medicines from the NHS based on a single non-peer reviewed, non-scientific report rather than available peer-reviewed literature.

Conclusions

The aim of NHS England's proposal is to help ensure that the, 'NHS achieves the greatest value from the money that it spends' (CD p.4 point 1.1), and that, 'CCGs can use their prescribing resources effectively and deliver best patient outcomes from the medicines that their local population uses' (CD p.4 point 1.1). [our use of underline]

These are admirable goals, particularly given the fact that the total amount of tax-payers money spent on items prescribed in primary care is now a staggering **£9.2 billion a year.**

Identifying medicines which should be stopped or only used under certain circumstances because they do not offer good value for money, is a logical place to start in attempting to reduce NHS prescription costs. However, suggesting that homeopathic medicines should be included on the list of the medicines which are never to be prescribed on the NHS in future is utterly illogical: NHS E is looking to make cost savings whilst ensuring best patient outcomes, yet removing homeopathy is highly likely to have the opposite effect on both counts.

In the development of this proposal, the joint working group were asked to assign one or more of the following recommendations to homeopathy (CD, p.5):

1.	Advise CCGs that prescribers in primary care should not initiate homeopathy for any new patient
2.	Advise CCGs to support prescribers in deprescribing homeopathy in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change
3.	Advise CCGs that if, in exceptional* circumstances, there is a clinical need for the item to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional * In this context, "exceptional circumstances" should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual
4.	Advise CCGs that all prescribing should be carried out by a specialist; and/or
5.	Advise CCGs that this item should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {item}.

Having seen the list of options available to the decision-makers behind this proposal, it is astonishing to see that they have selected options 1 and 2 for homeopathic medicines.

The existing provision of homeopathy on the NHS is captured within option 4 i.e. homeopathic medicines are prescribed by specialists who have the necessary training to assess when homeopathy is the most appropriate treatment option available, as well as the expertise needed to prescribe these medicines effectively.

Given the arguments presented above, NHS E should amend this proposal such that homeopathic medicines are assigned to option 4 only.

This will mean that the status quo is maintained, which common sense tells us is the most ethical, economical and efficient solution.

In conclusion, unless NHS England can provide clear evidence that a more clinically effective and cost-effective treatment option can be provided for the patients who currently use homeopathic medicines, this proposed removal of homeopathic prescriptions from the NHS cannot go ahead.

Homeopathic prescriptions should continue to be available, prescribed by specialist doctors, for those patients who need them.

Appendix 3 - Consultation Questions

Section 3: How will the guidance be updated and reviewed? Thinking about the process for future update and review of the guidance:

How do you feel about the proposed process for identification of items for possible addition to the guidance or indeed possible removal, from the guidance?

- Disagree

If needed, please provide further information

The document 'Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs' (hereafter the Consultation Document, CD), states that the joint clinical working group will be responsible for identifying which medicines should be 'retained, retired or added to the current guidance' (CD p.9).

It is apparent from the list of member organisations provided (CD Appendix1, p.29) that there is not a single party within this working group with the relevant and necessary specialist knowledge and expertise to assess homeopathic medicines.

The intention is for the joint working group to prioritise items based on criteria including safety, evidence of efficacy and cost to the NHS (CD p.9), yet there are no experts in homeopathic research to provide input on the existing peer-reviewed literature.

This lack of expertise is clearly evident in the working group's failure to cite appropriate and robust scientific evidence during this current consultation (see response to Section 4, p. 4).

Bearing in mind the working group's failure to assess the evidence base for efficacy and effectiveness of homeopathy in a useful and scientifically meaningful way this time, HRI therefore disagrees with the same working group being given the task of assessing homeopathic medicines in future.

Instead, the working group should include a sufficient number of experts to provide input on the following sub-fields of homeopathy research – safety, efficacy, clinical effectiveness and health economics – as well as doctors who prescribe homeopathic medicines.

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