the Nightingale Collaboration

Response to the Red Tape Challenge on the regulation of homeopathic and traditional herbal products

Alan Henness
Director

Maria MacLachlan
Director

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www.nightingale-collaboration.org
info@nightingale-collaboration.org

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Introduction

The Nightingale Collaboration[1] *challenges questionable claims made to the public by healthcare practitioners on their websites, in adverts and in their promotional and sales materials by bringing these to the attention of the appropriate regulatory bodies. The vast majority of these claims are made by practitioners of alternative therapies.*

We also strive to ensure that organisations representing healthcare practitioners have robust codes of conduct for their members that protect the public and that these are enforced.

The regulation of homeopathic and traditional herbal products has always been problematic and lies at the centre of much of the confusion in consumers' eyes about what constitutes legitimate, proven and evidence-based medicine.

It is clear that some of the regulations — particularly those surrounding homeopathic products — are not working to protect the public and we welcome the Government's commitment to investigate these under its Red Tape Challenge.

We are aware that much of the regulation of these products is mandated by various EU Directives, but we believe there are many actions that can be taken whilst still complying with those Directives to make these regulations work better for the public.

In this response, we recommend scrapping some regulations and amending others to reduce the burden of regulation and to increase the protection of consumers.

To help inform our response to the Red Tape Challenge, we conducted a survey of our supporters[2], asking various questions about the regulation of homeopathic and herbal products. In this response, we have quoted results obtained. We have included comments from some of the 190 supporters who responded to our survey in the appendix.

[1] 'The Nightingale Collaboration' <http://www.nightingale-collaboration.org/> [accessed 21 January 2012].
[2] 'Red Tape Challenge' <http://www.nightingale-collaboration.org/news/117-red-tape-challenge.html> [accessed 08 April 2012]

The role and authority of the MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) is widely recognised as the regulator of medicines. As such, products regulated by it are seen by consumers to have been given 'official' approval.

In their own words, the MHRA state they are:

> …responsible for ensuring that medicines and medical devices work, and are acceptably safe.

These functions are essential to ensure public safety and confidence in medicine, medical professionals and the healthcare system.

However, this role is severely tarnished because the MHRA regulates homeopathic products that do not work, yet allows them to be called 'medicines'.

The MHRA also regulates traditional herbal products, again allowing them to be labelled as 'medicines', but without requiring them to meet the same stringent safety requirements as other medicines nor requiring evidence of efficacy.

This two-tier system of regulation does not serve to protect the public and therefore is a failure in the most important aspects of the role of the MHRA and — because it is an executive agency of the Department of Health — of the Government.

This failure manifests itself in the false imprimatur MHRA regulation confers on homeopathic and traditional herbal products, their manufacturers, those who sell them to the public and their trade bodies.

We believe it also has the effect of denigrating those medicines that have had to pass the far more stringent requirements of a Marketing Authorisation.

The regulation of these products is not working.

The Government's Red Tape Challenge provides an opportunity to address these imbalances and to ensure that the regulations work better to ensure the protection of the public.

We therefore welcome the Red Tape Challenge's stated aim of listening to concerns about regulations that are not working as they should.

Regulation of homeopathic products

Homeopathic products are particularly problematic: there is no robust scientific evidence that they have any effect over placebo, with the overwhelming majority of trial results showing negative results. Meta-analyses and systematic reviews similarly do not provide any basis for homeopathic products to be called 'medicines'.

The House of Commons Science and Technology Committee (STC) concluded in their Evidence Check Report into homeopathy:

> In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos.[3]

Furthermore, given that homeopathic products typically contain no active ingredients, there is no plausible mechanism by which they could work.

Nevertheless, such products are allowed to be called 'medicines' or 'remedies' and are given a registration number that is essentially identical in form to that given to medicines with full Marketing Authorisation.

This confusion of disproven products with medicines that have had to undergo rigorous Marketing Authorisation lies at the heart of the problem.

There is a two-fold effect: it legitimises unproven and disproven homeopathic products and denigrates medicines that have had to undergo rigorous testing.

We wholeheartedly agree with the STC when it concluded:

> It is unacceptable for the MHRA to license placebo products—in this case sugar pills—conferring upon them some of the status of medicines. Even if medical claims on labels are prohibited, the MHRA's licensing itself lends direct credibility to a product. Licensing paves the way for retail in pharmacies and consequently the patient's view of the credibility of homeopathy may be further enhanced. We conclude that it is time to break this chain and, as the licensing regimes operated by the MHRA fail the Evidence Check, the MHRA should withdraw its discrete licensing schemes for homeopathic products.[4]

and

> By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse the use of placebo treatments, including homeopathy. Homeopathy should not be funded on the NHS and the MHRA should stop licensing homeopathic products.[5]

In our survey, 96% agreed or strongly agreed that being regulated by the MHRA misleads the public into thinking that homeopathic products are effective medicines.

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[3] '45.pdf', para. 70 <http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf> [accessed 8 April 2012].
[4] '45.pdf', para. 152.
[5] '45.pdf', para. 157.

We therefore call for the scrapping of all MHRA regulation of homeopathic products.

Further savings would be made if the Advisory Board on the Registration of Homoeopathic Products was also scrapped as it would perform no useful function if MHRA regulation was scrapped.

This will not stop the public being misled by the manufacturers and sellers of homeopathic products, but we believe that existing consumer protection legislation[6] — if properly enforced[7] — is sufficient to protect the public.

We would like to address the individual registration schemes separately.

Product Licenses of Right

We believe that the continuation of the 40-year-old concession to these homeopathic products is untenable. We note that the STC called for all homeopathic PLRs to be withdrawn and we are aware that the MHRA are minded to abolish these PLRs next April.

We urge the MHRA to scrap this unnecessary and anachronistic scheme by April 2013 at the latest.

Simplified Scheme

This scheme allows homeopathic products to be registered and labelled as 'medicines'. Although there are some safety and quality requirements, no evidence of efficacy is required.

The quality requirement is problematic because we believe that 'quality' is synonymous with 'effective' in the minds of the public.

Since homeopathic products are not medicines, the MHRA should cease their regulation for the reasons given earlier.

National Rules Scheme

This scheme was introduced in 2006 and it allows homeopathic products to have therapeutic indications — this misleads the public into thinking they can help/cure/alleviate the stated medical conditions or symptoms when no scientific evidence has been provided to substantiate those indications. Details from unscientific homeopathic provings, excerpts from homeopathic *materia medica* or other bibliographic data do not constitute good scientific evidence for indications and it is misleading to allow indications on such pseudo scientific grounds.

We are aware that one of the intentions of the National Rules Scheme was that manufacturers would be expected to apply to transfer PLR products to this Scheme.

After six years there is just one single product registered under the NRS and it therefore has completely failed in its intentions.

We believe there is no justification for not scrapping this unnecessary regulation.

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[6] 'The Consumer Protection from Unfair Trading Regulations 2008' <http://www.legislation.gov.uk/uksi/2008/1277/contents/made> [accessed 8 April 2012].

[7] 'Spurious Claims for Health-care Products: An Experimental Approach to Evaluating Current UK Legislation and Its Implementation' <http://mlj.rsmjournals.com/content/80/1/13.long> [accessed 13 March 2012].

'Right-touch' regulation of homeopathic products

The only reason we can see for not scrapping the MHRA regulation of homeopathic products are the Government's obligations under various EU Directives.

If these responsibilities must be honoured, we urge the Government to consider whether the MHRA, as regulator of medicines, medical devices, medical equipment, etc is the most appropriate body to regulate homeopathic products.

In our survey, 86% agreed or strongly agreed that homeopathic products should not be regulated by the MHRA.

We believe that the 'right-touch' regulation of homeopathic products could be achieved by a body such as the Food Standards Agency and that homeopathic products more rightly fit within their purview. We note that the regulation of food supplements falls within the remit of the FSA.

However, we note that the FSA is committed to being science and evidence-based and clearly homeopathic products cannot fit within any such values.

We do not think it appropriate for the regulation of homeopathic products be given to any voluntary regulator such as the Complementary and Natural Healthcare Council.

Labelling of homeopathic products

In our survey, 93% agreed or strongly agreed that the current wording on registered homeopathic products is misleading.

94% agreed or strongly agreed that homeopathic products should not be permitted to have indications.

The prescribed wording on homeopathic products under the Simplified Scheme is currently:

> A homeopathic medicinal product without approved therapeutic indications.

This wording is problematic because it is both misleading and confusing to consumers.

As stated previously, it cannot be correct to allow products that have not demonstrated any medicinal effect to be called medicines. Calling these products 'homeopathic medicinal products' misleads some consumers into thinking that homeopathic products are medicines. This applies to the product the label is attached to and, by extension, that other homeopathic products are also medicines.

The same argument applies to the word 'remedy' — we believe this also implies that it is efficacious.

> without approved therapeutic indications

This is a technical phrase loaded with jargon and one that confuses consumers. We do not believe that all consumers will understand from it that the manufacturer is prohibited from listing medical conditions the product can be used for because no robust evidence has been supplied.

It also might be misunderstood to imply that there are *unapproved* therapeutic indications, even though there are no *approved* ones.

Under the National Rules Scheme, the prescribed wording is:

> A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of [list of indications]

Again, examining this:

> A homeopathic medicinal product

See above.

> used within the homeopathic tradition

This is, in itself, irrelevant and misleading. 'Tradition' implies that homeopathy is some form of ancient system that is simply different to conventional medicine and its age confers some kind of legitimacy to it. The facts are different however. Even though homeopathy was invented over 200 years ago, no robust evidence of its efficacy has ever been established.

> for the symptomatic relief of [list of indications]

This gives the impression that these products can relieve the listed symptoms when, in fact, there is no scientific evidence to support that assertion and none was required nor supplied to the MHRA in order to obtain a registration number.

Consequences of inaccurate labelling

Inaccurate labelling of products is misleading and potentially fraudulent and costs consumers money. Inaccurate labelling of products purporting to be medicines is very serious because it can lead to someone delaying or forgoing possibly necessary and urgent medical attention from a properly qualified medical practitioner.

We do not believe that such incidents are widely reported, so it is difficult to quantify the harm done, but there have been many cases where people have relied on homeopathic products and advice from homeopaths that have resulted in serious medical conditions and sometimes even death from a condition that was eminently treatable by conventional treatments.

For these reasons, we believe that the regulation — which purports to protect the public — fails.

Ingredients

The majority of homeopathic products contain only sucrose, lactose or other excipients.

Those labelled as containing dilutions greater than 24 X/12C (in the homeopathic nomenclature) of the 'mother tincture' are typically unlikely to contain even one molecule of it.

It is not possible to measure the quantity of any such ingredient.

It is therefore misleading to describe them as containing any other ingredients — never mind ones that could be described as active — as they are currently allowed to do under the regulations.

Because of this, allowing products to list other ingredients misleads consumers into thinking that the product does actually contain something active when this is not the case.

Stating a quantity of an 'ingredient' in any homeopathic nomenclature (usually X or C) is misleading as, until it has been clearly explained, most consumers will not understand that this means there is unlikely to be even one molecule of the putative principal ingredient in the product.

We therefore recommend that the listing of any 'ingredient' where the product contains no measurable quantity of it should be prohibited.

Alternatively, the quantities of ingredients should be in the same form as other ingredients, ie either as weight or volume or as a percentage of the total weight or volume and in line with other weights and measures regulations.

Recommended labelling

So that consumers are not misled by the inaccurate labelling currently on homeopathic products, we recommend that labelling requirements are replaced by text that more accurately reflect their true nature. For example:

- This product is not a medicine.
- There is no scientific evidence that this product is effective.
- This product contains no active ingredients.

We urge the MHRA to reconsider the way homeopathic products are labelled, ensuring they are written in plain English and free of jargon so that their meaning is easily understood by the public. This public understanding should be verified by rigorous testing.

Regulation of traditional herbal products

Many herbal products have established and plausible pharmacological effects and, as such, there is a need for some measure of control over public availability.

At present, for some 'traditional' herbal products, this is achieved by regulation by the MHRA under its Traditional Herbal Registration Scheme (THRS).

Herbal products for which efficacy can be demonstrated are not normally allowed to be registered under this scheme[8] and registration does not require any evidence of efficacy to be provided.

This scheme allows herbal products to have therapeutic indications, even though no evidence to substantiate such claims has been provided.

Safety is 'assured' by insisting on evidence that the product has been in use for 30 years with no problems, 15 of these in the EU, with the applicant providing a bibliographic review of safety data of the herb and an expert's report, rather than any new hard safety data on the product concerned.

To ensure the product is of good quality, to support safety, manufacturers have to abide by Good Manufacturing Procedures — this helps ensure the products only contain what they are allowed to contain and are not contaminated or adulterated, as has happened with some unregistered products.

This regulation undoubtedly offers some measure of protection to the public and in that regard, the regulations can be considered effective.

However, it allows these products to be referred to as 'medicines' and we believe this gives the impression that have had to pass the same stringent requirements that pharmaceutical medicines have to before being given a Marketing Authorisation when this is not the case.

On the contrary, this is another two-tier system of medicines regulation, with stringent requirements for some and lax requirements for others.

We strongly believe this confuses and misleads consumers and in this regard, the regulations are failing to protect the public.

[8] 'How to Register Your Product Under the Traditional Herbal Medicines Registration Scheme: Overview and Scope of the EU Directive 2004 2004/24/EC on Traditional Herbal Medicinal Products : MHRA', para. 11 <http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicinesregulation/RegisteredTraditionalHerbalMedicines/HowtoregisteryourproductundertheTraditionalHerbalMedicinesRegistrationScheme/OverviewandscopeoftheEUDirective2004200424EConTraditionalHerbalMedicinalProducts/index.htm#s10> [accessed 10 April 2012].

'Right-touch' regulation of herbal products

We are aware of complaints from manufacturers, sellers and supporters of traditional herbal products that even this lax form of MHRA regulation is burdensome, prohibitively expensive and restricts consumer choice. We do not agree with these assertions and we urge the MHRA not to be swayed to simplify the regulations any further or to absorb any of the costs.

In our survey, 61% disagreed or strongly disagreed that the current regulation of herbal products was burdensome and 72% disagreed or strongly disagreed that regulation of herbal products should be scrapped.

Even if the regulations were burdensome, that is no reason to scrap them. The requirements are the absolute minimum required to give a small measure of protection to consumers who may be unaware of the issues surrounding regulation.

In our survey, 91% agreed or strongly agreed that the protection of the public is more important than choice.

We strongly urge the MHRA not to lower the hurdle of regulation even further.

In our survey, 97% agreed or strongly agreed that herbal products should be regulated and have to meet the same requirements for efficacy and safety as conventional medicines.

We appreciate there is a dilemma here: herbal products need to be regulated, yet they are highly unlikely to meet the stringent requirements of Marketing Authorisation.

We therefore urge the MHRA to propose possible solutions to this and consult the public and interested parties on the best way forward to ensure that regulation achieves its aim of protecting the public.

Labelling of herbal products

Under the THRS, a herbal product must display its registration number and the following text:

> Traditional herbal medicinal product for use in [specified permitted indications] exclusively based upon long-standing use as a traditional remedy.

This wording is problematic and misleading to consumers.

In our survey, 82% agreed or strongly agreed that the current wording on registered herbal products is misleading.

For the reasons given above, we do not believe it is appropriate to allow these products to be called 'medicinal' because this implies that they have been shown to be efficacious.

The same argument applies to the word 'remedy' — we believe this also implies that it is efficacious.

We find the word 'traditional' problematic. It is, essentially, meaningless since it confers no additional authority that the products are safe or effective, yet we believe it will be understood by consumers as implying that it has been used for perhaps centuries or millennia and that this confers a good measure of confidence that it safe and effective.

Conclusion

The current regulation of homeopathic and herbal products by the MHRA is not satisfactory and does not work to protect consumers.

We have made various recommendations throughout our response and we trust that they will be given serious consideration by Ministers in their review of the medicines regulations.

Appendix

Below are comments made by some of the respondents to our supporters' survey. We do not necessarily endorse these views.

1. Homeopathy worries me the most. It's magic water and should not be given credence by alleged responsible regulators. Herbals might in some cases have some actual effects though this is also usually of doubtful efficacy. Unsure on the 'regulation should be scrapped' questions. I would agree if this meant that the sellers couldn't make efficacy claims. I might disagree if this left them free to sell whatever they like.
2. Homeopathic products are sugar pills. They have no effect but can mislead the public into thinking they are effective. This may cause the public to take homeopathic remedies rather than remedies that may work. Homeopathy can kill because it fails to treat illness effectively. Homeopathic remedies must be regulated and labelled that they have no effect on any condition. Herbal remedies may have some effect, but just because they are natural doesn't mean they are not dangerous. Deadly nightshade is entirely natural and can kill. Herbal remedies should be regulated as all medicines are regulated.
3. I have seen no evidence that convinces me that homeopathic so-called remedies have any beneficial effect beyond placebo and that only with those susceptible to such things. Whilst I think that there are some efficacious herbal remedies I do not think they are always either safe or effective. They should never take the place of a medical examination and approved evidence based medicine.
4. I think any product that makes medical claims, even fairly weak ones like remedy for symptoms of whatever, should have to prove efficacy. If cannot prove efficacy, should be statement that there is no evidence of effectiveness.
5. All such products must be clearly labelled along the lines of "There is little evidence that this product works any better than a placebo"
6. The only things that should have efficacy statements are those that have been tested scientifically and proven to have a measurable effect. Unfortunately there are certain foods which do appear to have scientific effects (e.g. Certain yoghurts which speed recovery time after stomach illnesses) yet they cannot claim this as they have not been thoroughly tested - as medicines are. Why should herbal remedies and homeopathic remedies have the privilege of having statements that imply efficacy??
7. The purpose of healthcare regulation is ultimately to ensure patient safety. With medicinal products, the primary concerns should therefore be the products' safety and efficacy, not protection of traditional beliefs or manufacturing methods. So I see no reason to have different regulatory systems for herbal/homeopathic products. All 'medicinal'/pharmaceutical products (traditional or modern, 'natural' or otherwise) should be subject to the same regulation and the same standards regarding safety/efficacy/indications/sale. I think much of the public assume this is already the case, so under the current system they are likely to be misled.
8. Have agreed regulation should be scrapped, but if they are to be regulated, should have to have the same level of evidence as pharmaceutical products - homeopathic/herbal manufacturers should fund clinical trials.
9. I think these "remedies" should be licensed but in such a way that they need to carry clear and prominent disclaimers until there is proper evidence that they are defective. Something along the lines of "there is no evidence that this product is effective in treating any medical condition" in large "smoking kills" style lettering.
10. there are a few false dichotomies there can be choice and protection of the public by appropriate labelling and education. while the current regulation of homeopathic products falsely endorses their use appropriate control of any product for which a health claim is made would enable the informed choice by the public.

11. (1) Homeopathic I understand that the existing wording is forced by EU rules. Ii that is so, and no derogation is possible, then an additional label should be added which states explicitly that the product contains none of the ingredient specified on the label (for any dilution above 12x), It should also state that there is no reason to think that there is effective tor any condition. The current labelling about storage and overdose is scientifically absurd and should be removed. If this is done the homeopathic products committee could be disbanded. (2) Herbal The need to prevent toxic products being marketed (either because the herbs themselves are toxic or because of contamination). Since herbal medicine are just drugs, I see no reason why they should not be regulated like any other drug. Since, as the MHRA itself has stated, there is no good reason to think that most of them work. As a result, most of them would have to come off the market. This would be the sensible thing to do from the point of view of medicine and science. If it were considered to be politically unacceptable, then at least the label should tell the literal truth, that there is no good reason to think that the product is effective. The MHRA could be saved much work in pursuing false claims for medical effectiveness if the proposed reorganisation of Trading Standards made them effective in the medical area. At present they have the statutory duty to enforce the Consumer Protection Regulations (2008) but fail to do so.
12. Medicines are not alternative. They are just medicines and only so if the efficacy is proven in trials.
13. There is no reason whatsoever that herbal and homeopathic medicines shouldn't have to undergo the same level of testing for safety and efficacy as any other drug if they are as effective as their followers claim.
14. Why is the MHRA wanting to deliver an increase in “choice and opportunity” when it should be addressing, very thoroughly, efficacy and safety concerns? Doesn’t it realise that all homeopathic products, and most herbal ones, are not supported by robust RCT evidence? Is it also not aware that some homeopathic and herbal products have been known to be contaminated with heavy metals and pharmacological compounds, and yet there appears to be no system in place for reporting harms? Such harms would also include adverse events caused by herbal interactions with conventional medicines. As things stand, the MHRA is leaving itself open to accusations of fraudulent marketing. Consumers need protecting, not double standards. In failing to regulate these products to the same standards as real medicine it looks like the MHRA’s stated principles are being abandoned in favour of manufacturing companies’ profits.
15. I find it iniquitous that regulated products such as homeopathic remedies do not have to demonstrate any evidence of efficacy. This is a double standard that facilitates the promotion of these products as somehow being "approved". The inference drawn by the public is that this "approval" implies these products have been proved to be effective, which is not the case.
16. Homeopathy has been shown repeatedly over a period of 200 years to be ineffective. Someone with even a small understanding of the principles behind it should be able to see that it could not work and is counter intuitive to all human experience and objectively gained knowledge. This leads to a conclusion that any practicing homeopath is either very easily convinced of anything whether true or false (gullible) or understands there's nothing in it but still practices it anyway (effectively a legal con artist). In either position the person should not be allowed to give any form of professional medical advice. There is a very ‘cult’ like quality to the industry (one man’s ideas, a process that is enshrined in a single book, defensive and aggressive response to any criticism). Each individual herbal product should be treated individually as any other medicine would as they may be effective. If ineffective or dangerous then they should not be sold.
17. If a product, such as a herbal treatments, has active ingredients that is supplied as a treatment then it should have the same need for evidence of effectiveness, safety and dosing as standard medications and licensed appropriately. If a product has no active ingredients, such as homeopathy products, they should not be able to claim therapeutic effects for any medical problems and should not be registered as drugs/medications or be able to claim medicinal benefits.

18. If businesses wish to sell their products as medicines, they should adhere to the same, stringently high standards. Entrepreneurial spirit must not be allowed to undermine the public's health, nor its confidence in genuine medicine.
19. Homeopathic 'medicines' contain no active ingredient whatsoever. This fact should be displayed prominently on all packaging.
20. In a £multi-billion industry there is no excuse for them not being able to supply some clinical test data for herbal products to prove efficacy. If this happens and efficacy is proven then obviously it becomes "medicine" Homeopathy is basically just a scam and I don't know how they have got away with it for so long.
21. Homeopathic and herbal medicines should be treated exactly as any other type of medicines: if there is proper evidence they work without unacceptable side effects then they should be within the remit of the MHRA; if there isn't, this should be clearly indicated on the packaging.
22. People can be gullible. They assume that products are efficacious and safe, without evidence. A lack of proper labelling reinforces this false impression.
23. No products, herbal or homeopathic, should be allowed to make claims of efficacy or safety until and unless they have met the same strict criteria as all real medicines. They should be forced to state on the packaging, in an easily read font, that they have not been proved to be either safe or effective until they have met the above criteria.
24. None of these product classes should be regulated as Medicines unless they wish to make medicinal claims when they should be subjected to full licensing criteria. As belief based medicines they should be totally separated & classified (Health integrators?) from evidence based preparations. Compulsory registration of full formulas with precise identities, manufacture by licensed producers and bold labelling to distinguish them from evidence based. In stores and practices these items must be on display in clearly defined areas eg as cosmetic is separated from dental in pharmacies. A legal leaflet to be available at point of sale indicating to consumers that these items are not approved by government and included in package by manufacturer. All mail order/internet supplies covered by these rules ie all parcels to include the legal details on the point of sale leaflet in stores. In this way the impact of internet supplies would be lessened. Such r & d rules to apply to "dietary" items too.
25. Homeopathic products have been shown to have no greater efficacy above that of placebo. The general public do not show a great deal of scientific literacy and consequently, they are easily misled by the wording on products of this type into believing that they are effective for a variety of conditions. Herbal products may be effective in some cases. However, the public tend to have a misperception that they are safer than conventional medicines on the basis that they are 'natural'. This is very misleading. A number of plants which are natural such as deadly nightshade, hemlock, death caps etc are equally natural but deadly. There is therefore a case for regulation of these products and permitted wording on packaging or in advertising to be increased.
26. I was "treated" with homeopathic stuff for asthma as a kid - while my parents were sort-of acting in good faith, I get angry at the thought that (even well meaning) parents could be naively complicit in letting an illness go on, instead of getting real medicine. I'm now, as an adult, on quite a lot of prescribed medication, and I keep much better than I did when I was young. As a child, I didn't have that choice. Could it be made illegal for shops to sell these sorts of fairy-medicine for the use of a child, just like it's illegal to sell some other, otherwise-legal, products like cigarettes or adult-rated films if they're for someone under 16? At least adults can choose to go down that path if they want to.
27. Herbal and homeopathic medications should be regulated on the same basis as real medicine, the current MHRA procedures just legitimise Quackery.
28. I feel extremely strongly that people are unaware of what utter nonsense homeopathy is. It is selling water and sugar pills. So called homeopaths are either fraudulent or deluded. I was taken to a homeopath as a child, and took the "remedy" with associated magic routine, my illness got better (which it would have done, anyway- chronic acute tonsillitis). Later, in desperation (I had psoriasis) I visited a Chinese

herbalist. Again, the condition was completely cured. I am less informed about herbal products, however, and felt less able to comment.

29. Homoeopathic "remedies" should have something along the following lines: "Contains only water, and in tests has been shown to have much the same effectiveness as water"; The problem with herbal remedies is that there's nobody to pay for the tests - maybe there ought to be a licensing schema whereby if someone were to pay to prove that a particular herbal medicine worked for a particular condition, they could be given a licence to sell it. Might be too complicated to administer, though.
30. I am outraged by the fact that the NHS continues to fund homeopathic hospitals and treatments. As regards herbal remedies, it seems likely that some are helpful, and some make no difference (apart from as a placebo), while some have been shown to be harmful. It should not be possible to sell anything as a remedy for any condition unless it has been subject to the same testing for efficacy and harm as anything sold/prescribed as a 'conventional' medicine.
31. Regulation of herbal products/homeppathy should be scrapped - or should be effective - that is, homeopathic/herbal (and other) remedies should only be approved if they can work under a normal double-blind trial.
32. Homeopathic products: These should not be called `medicines'. There should be one scheme for regulation, requiring products to demonstrate efficacy and safety in exactly the same way as real medicines. Such products which fail the test (or choose not to be tested) should be taken out of MHRA regulation, but will remain regulated by consumer protection legislation. Herbal products: No indications should be allowed unless robust clinical trial data are available. Traditional use should not be mentioned on labels, or used as a justification for an indication.
33. It is shocking that a practice such as homeopathy is offered in the NHS without any evidence of efficacy (the opposite is true - studies show homeopathic treatments do not work beyond the placebo effect). Homeopathy need only demonstrate its 'proving' (nothing to do with efficacy, safety or the scientific method). I do not want a healthcare system that is consumer led and treatments are offered on two criteria: does the customer want this? Is it cost effective? If herbal treatments are proven to work they should be offered on a par with any other treatment. Any herbal treatment that has been proven not to work gets thrown out (why is nothing thrown out in the world of alternative medicine?).
34. Homeopathic products contain no active ingredients and are therefore not medications - regulating them as such gives them the air of an actual medication, rather than the expensive water or sugar pills that they are. If they are to be regulated, they should be subject to the same burden of proof of efficacy as "actual" medications. Herbal products can be dangerous (there have been cases of usage of dangerous substances in Chinese medicine, for example) and as such should be regulated and subject to the same burden of proof, re. efficacy, etc. as actual medications.
35. There should be no distinction in government regulation between different 'kinds' of medicines. There should only be one kind of medicinal product license, and each sold product should have the following attributes: 1. It has been shown to work, i.e. is beneficial to patients in clinical trials 2. It has been shown to be safe, i.e. it has known and acceptable side-effects given its application 3. There is a clear labelling showing who made it, and who authorised it Quacks will continue to sell nonsense, but the Government should not encourage it by providing 'regulation' and the misleading labelling that goes with it.
36. I used to use homeopathic products because I believed there was something in them, that 'they' would not cause them to be licensed and regulated if there was nothing in them. Then I found out there was nothing in them and I had in fact been conned. Seeing water and/or sugar pills instead of actual treatments is immoral, unless you are going to openly say they are placebos. As for herbal medicines, they can be effective and so should be regulated like all medicines. It makes no scientific sense that taking a varying dosage in its botanical form is somehow better than taking a stable dosage in its pharmaceutical form.
37. A general problem in dealing with homeopathy is the fact that there is a widespread public lack of knowledge about its exact nature and it is often lumped together with herbal and 'natural' products. In

particular, many people are just not aware of the dilution process used in the preparation of homeopathic products. Hence, treating them with separate regulation regimes may be confusing to many.

38. If any herbal remedies have any effect which some do have they should be regulated as for ordinary medicines. Homeopathic stuff is of course completely safe because it is no more than placebo and they should not be allowed to make any claims at all. Neither should be allowed to make any claims whatsoever unless evidenced.
39. If regulated by the MHRA, these products should meet the same standards of clinical efficacy and safety
40. Homeopathy and herbal medicines need to be regulated in order to protect the public. However, licensing homeopathy as a medicine and allowing indications to be given on packaging is misleading. Herbal products differ in that in some cases, there may actually evidence of efficacy and in some cases, there could also be also be side-effects. These need to be regulated but it's important that the public are not misled into believing that in being regulated, this suggests they are safe and effective (since they do not have to meet the same requirements as conventional medicines). The MHRA also need to be seen to take action on unlicensed and unregistered herbal, homeopathic and other alternative medicines.
41. Scrapping the regulation of homeopathic products would lead to a free for all without, per se, diminishing the public's view that these are effective. Homeopathic products should be regulated on the grounds that they are products that "purport to be medical" and should be required to have a full disclosure label reading something like: "properly conducted scientific tests do not reveal any beneficial effect of this product beyond a placebo effect. This product is not a medical product"
42. herbal and homeopathic medicine have been wrongly endorsed as a valid alternative to conventional evidence-based medicine. Also, medicines have to show that they fully tested and show no overlap (or similar) to other medicines prior to licensing.
43. Homeopathic products need not be licensed as they are not medicines but should bear labelling stating that they are diluted to such an extent that they contain no active ingredients and there is currently no evidence that shows they have any therapeutic effect beyond placebo. Advertising for homeopathic products should include the above information and should not be allowed to claim therapeutic effect. Medical professionals and pharmacists who recommend homeopathic products should be disciplined by their governing body. All herbal products should be regulated the same as conventional medicines. Current regulation should be extended to include products sold after a one to one consultation with a herbalist.
44. Homeopathic products should have to meet the same requirements for efficacy and safety as conventional medicines.
45. MHRA regulation only adds to the general feeling that "it must be OK". It also alarms me that people think "natural" means "harmless"; also that homeopathy is "herbal medicine" when there is no medicine in it. Something that contains no active ingredient should not be regulated by the MHRA. It should state that it contains sugar and nothing else.
46. No product, regardless of how it's made and what from, should be marketed to the public as medicine without independently substantiated proof that it is more effective than placebo at treating any condition which it claims to so do.
47. Every homeopathic and herbal remedy should be clearly labelled to show how effective it is, according to reliable clinical trials.
48. There should be regulation of these products but it should be really simple: if you want to carry indications then you must pass the same test as a pharmaceutical making the same claim, if you can't pass the hurdle of RCT evidence then the packet should contain a disclaimer that it is not a medicinal product and has not been tested or approved for treatment of any condition.
49. The public need to be informed as to the risk they are taking, and what the actual proven effects are. There is no reason that this needs to stop them having choice.
50. Two different product types are being discussed here, and they should be treated separately to avoid confusion by the general public since they are often thought to be similar or the same. Herbal medicines

may contain active ingredient. Indeed, many medicines were original identified as herbal derivatives, or are now based upon derivatives of herbal product. As such, herbal medicines having pharmacologically active ingredient will need to be tested and produced to the same standards as conventional medicines to avoid both contamination issues and untoward pharmacological doses resulting in clinical problems (as has been documented elsewhere). Homeopathic medicines contain no active ingredient and have never been shown to be efficacious in stringent clinical trials. They should be labelled as such, to allow the public to make informed decisions on purchase. Any selling of homeopathic remedies as a treatment for any clinical condition should be banned and be made punishable by the courts.

51. I have no problem with one to one consultations with a herbalist, but many are duped into thinking over the counter 'remedies' are 'natural' and safe. If sold over the counter they need the same exacting regulation as any other medicine.
52. A clear distinction needs to be drawn between products which have proven medical efficacy and those that don't. Allowing homeopathic products to list indications for which there is no proven basis is misleading and potentially dangerous, principally for the following reason: It creates a false sense of validity for non-evidence-based treatment, leading to a mistrust of proven avenues of medical treatment. This mistrust is evidenced when an individual with a potentially serious medical concern (e.g. malarial prophylaxis) turns to homeopathy as a first port of call. Medicine and health supplement regulation should be divided into 2 camps: those treatments which are supported by a sufficiently rigorous level of evidence and those which are not. The latter camp should include clear wording to the effect " There is insufficient evidence to support the use of this product for the treatment of any medical condition".
53. ANY implication or inference that there's efficacy or zero detriment from so called Alternative Medication will inevitable create a passive acceptance of their being of potential benefit. No not consciously, an Occam's Razor application of this misinformation will drive some people to AltMed as an alternative to or dilution of proper, tested medication. AltMed is intrinsically harmful to the nation's health and the welfare of it's populace. Please stop this bogus trade from distracting people out of proper medication: it delays or prevents treatments that are evidentially likely to succeed. It funds the practice of charlatans.
54. Homeopathy is an elaborate con trick played on gullible or desperate people.
55. I strongly feel that all medicines that the public have available to them should be held to the same high standards of safety and efficacy. To have a double standard where conventional treatments maintain high levels of testing while herbal and homeopathic remedies need only produce "pharmacopoeias" and histories of traditional use is absurd at best and dangerous at worst.
56. If a product has a proven physiological affect upon the human body it should be subject to same regulations as any other medicinal/Drug product.
57. It appears that the guiding principles behind this governments actions in relation to this initiative are light touch regulation and freedom of choice. Free choice is only possible when accurate information is available. This fits well with the idea of short warning statements indicating the limitations and possible harms of the specific therapy that might be displayed in alternative therapists businesses and printed on remedies. Other regulation might then be removed, where possible within European law, leaving serious wrong doing to be investigated by the MHRA and trading standards and misleading claims in advertising being left to the ASA.
58. Any remedy sold should have to undergo the same rigorous tests regardless of the origin of the system of medicine. If a herb works it is medicinal, and should be subject to the same legislation as any other pharmaceutical. It's a cliché, but herbs etc that have been proven to work are called medicine, everything else is just pot pourri, or dangerous pot pourri. With the exception of homeopathy which is very expensive sugar. If it's a drug, regardless of origin, there should be one standard for safety AND efficacy, no exceptions for TCM, homeopathy or anything else.
59. It is important that regulation of homeopathy and of herbal remedies is done in such a way that it is made very clear the difference between the two. That is, that homeopathic products have absolutely no active ingredient, whereas herbal remedies might. In the latter case, because of the real threat of side effects,

herbal remedies should be subject to exactly the same regulation as pharmaceutical products. In the former case, no particular regulation is necessary, beyond a requirement that homeopathic products should be clearly labelled as containing no active ingredient.

60. As a doctor I recognise the usefulness of the placebo effect. There are many conditions for which there are few effective treatments and for which symptomatic control is the main aim. We have no real evidence for a lot of treatments prescribed - such as antidepressants for mild depression, NSAID gel for back pain, etc - but we use them as this makes the patient feel better. My personal feeling is that we should allow homeopathic medicines to be advertised as helping with this or that symptom, as they inevitably do, through the placebo effect. If it helps people, there is no real harm to that. The only real harm is when people think that homoeopathy treats disease, and as such don't use genuine medicine where it is needed. I think therefore that the marketing of homoeopathy should be changed, so homoeopathy should be allowed to make claims about symptomatic benefit but never be allowed to make claims about treatment of the underlying disease.
61. "natural" does not mean "safe" - any number of natural plants and herbs will kill very effectively so all products with any kind of active ingredient must be regulated. Homeopathic products contain no active ingredients so do not need to be regulated (and regulation suggests that they might have some effect)
62. Evidence must outweigh 'tradition', 'choice' and political posturing in this area.
63. Regulate both herbal and homeopathic 'medicines' in exactly the same way as normal medicines - hold them to the same standard of proof and testing before allowing them to be licensed, and ban any that can't pass that test. Anything that can't be distinguished from placebo in an independent double-blind trial should not be sold as a medical product. The current situation makes it too easy for disreputable homeopathists (ie all of them) and herbalists to make money out of vulnerable, insufficiently educated customers. Unproven homeopathic/herbal remedies should not be available from pharmacists.