

## Summary: Intervention & Options

<b>Department /Agency:</b> <b>MHRA</b>	<b>Title:</b> <b>Outline impact Assessment on the review and transfer of some herbal products with a marketing authorisation to traditional herbal registration status</b>	
<b>Stage: Final Outline IA</b>	<b>Version: 3</b>	<b>Date: Jan 2009</b>
<b>Related Publications:</b>		

### Available to view or download at:

<http://www.mhra.gov.uk>

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### What is the problem under consideration? Why is government intervention necessary?

The problem is that for historic reasons a proportion of the mostly longstanding herbal medicines on the UK market have a marketing authorisation (MA) (for which regulatory requirements include demonstration of efficacy) whereas some of these products with MAs now fall to be regulated by Directive 2004/24/EC, a regulatory scheme for herbal medicines in which evidence of traditional use replaces the efficacy requirement.

The difficulties associated with this scenario are that (a) there is legal risk and regulatory uncertainty if MHRA takes no action to regularise the position of products that, following the end of the transitional period in April 2011 afforded by Directive 2004/24/EC, will overtly be in the incorrect regulatory category (b) it will become increasingly confusing to consumers to have two different categories of "traditional use" herbal medicines and (c) transparency and fair competition is not encouraged by the current confused situation.

The requirement for an impact assessment is not clear cut. There are existing requirements - both for companies to keep their dossiers and product information up to date and for the MHRA as regulator to take action if it believes that products may not in fact meet all the relevant requirements for an MA. The action represents normal, ongoing regulatory action and no costs beyond the normal regulatory requirements apply. However, MHRA considers that production of at least an outline IA is helpful given the potential number of products affected and given that potentially unnecessary costs could occur if the MHRA were to carry out its responsibilities without regard to the effect on those companies most affected. Significant costs could be incurred by companies if the programme were to be deferred, and subsequently had to be carried through to a much tighter timetable and in a less planned manner. It is not therefore necessary to proceed beyond outline impact assessment stage.

### What are the policy objectives and the intended effects?

To ensure that OTC herbal medicines are ultimately in the correct regulatory category in line with the legislation – ie as MAs where standards of efficacy are met and within the THR scheme where efficacy standards for an MA are not met but there is evidence of traditional use.

This will avoid legal risk and regulatory uncertainty; remove a source of confusion for consumers and maximise fair competition in the herbal medicines sector.

The objective is to achieve the change smoothly in a flexible programme that allows companies to plan and does not deflect companies from the priority of submitting traditional herbal registration (THR) applications for existing unlicensed herbal remedies marketed under s12(2) of the Medicines Act 1968.

What policy options have been considered? Please justify any preferred option.

Option 1 – do nothing

Option 2 - instigate programme to review herbal MAs leading to likely transfer of some products to THR status (including some flexibilities/benefits for companies)

Option 3 – as for 2 but without those flexibilities and benefits for companies

Option 2 is the favoured option on the basis that it will clearly meet the stated objectives while avoiding the drawbacks inherent in both Options 1 and 3.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The programme will be monitored and reviewed 6 monthly (or more often). In the short term the emphasis will be on seeking to avoid or contain any unexpected practical difficulties. More substantive review will take place by 2012 at the latest to ensure benefits are on track for delivery.

## Summary: Analysis & Evidence

<b>Policy Option:</b>	<b>Description:</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups' N/A		
	<b>One-off</b> (Transition) <b>Yrs</b>			
	£			
	<b>Average Annual Cost</b> (excluding one-off)			
	£	<b>Total Cost (PV)</b>	£	
Other <b>key non-monetised costs</b> by 'main affected groups'				

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups' N/A		
	<b>One-off</b> <b>Yrs</b>			
	£			
	<b>Average Annual Benefit</b> (excluding one-off)			
	£	<b>Total Benefit (PV)</b>	£	
Other <b>key non-monetised benefits</b> by 'main affected groups'				
A possibly small number of currently non marketed herbal MAs that would otherwise disappear as a result of the Sunset clause may regain commercial viability as a result of the greater flexibility offered by certain aspects of the THR scheme. Cannot realistically be monetised at this stage.				

Key Assumptions/Sensitivities/Risks
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Price Base Year	Time Period Years	<b>Net Benefit Range (NPV)</b> £ N/A	<b>NET BENEFIT (NPV Best estimate)</b> £ N/A
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What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	April 2009
Which organisation(s) will enforce the policy?	MHRA
What is the total annual cost of enforcement for these organisations?	£ Normal
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£ NA
What is the value of changes in greenhouse gas emissions?	£ Nil
Will the proposal have a significant impact on competition?	Modest improvement
Annual cost (£-£) per organisation (excluding one-off) (Within existing requirement to comply with)	Micro Nil    Small Nil    Medium Nil    Large Nil
Are any of these organisations exempt?	No    No    N/A    N/A

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase of    £ N/A	Decrease of    £    N/A	<b>Net Impact</b> £ N/A

Key:    Annual costs and benefits: Constant Prices    (Net) Present Value

# Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

## 1. TITLE OF PROPOSAL

Review of existing herbal Marketing Authorisations (MAs)

## 2. PURPOSE AND INTENDED EFFECT OF MEASURE

### (i) The objective

To ensure that regulated herbal medicines are in the appropriate regulatory category in line with European and UK legislation, thereby minimising legal risk and regulatory uncertainty that would arise from overt non compliance, also removing a source of confusion for consumers and ensuring a level playing field for industry.

### (ii) Background

European Directive 2004/24/EC on traditional herbal medicinal products was brought forward specifically in recognition of the position that for many herbal medicines it was difficult for companies to meet the full requirements for a marketing authorisation, particularly in relation to efficacy, as are required under Directive 2001/83/EC. Many EU Member States had pragmatic national arrangements permitting herbal medicines to remain on the market, whether as licensed or unlicensed products.

The Directive therefore required Member States to put in place specific regulatory arrangements for those traditional herbal medicinal products, suitable for use without medical supervision, for which there was evidence of traditional use but insufficient evidence of efficacy to meet the requirements for a marketing authorisation (MA). The legal effect of the Directive is not restricted to those medicinal products which are, or have been, unlicensed (for example, in the UK, unlicensed herbal remedies under Section 12(2) of the Medicines Act 1968).

In the UK many herbal medicines were originally given a product licence of right (PLR) when medicines licensing was introduced and were subsequently granted a full MA following the Review of Medicines. The review of herbal medicines commenced in 1988 and was completed mid 1990.

The CRM (Committee on Review of Medicines) recognised that these traditional products could not be assessed in the normal way and agreed that provided the product was intended for a minor condition, suitable for self-diagnosis then evidence documenting the use of the product would be accepted in place of results of pharmacological tests and clinical trials. Where licences were granted in such circumstances they were required to be labelled with a statement along the lines of '*a herbal remedy, traditionally used for the symptomatic relief of ...If symptoms persist, consult your doctor.*' In the case of more serious disease conditions the CRM advised that it was not appropriate to relax the requirements for proof of efficacy.

This approach was in effect therefore a precursor of that which was subsequently taken in Directive 2004/24/EC. The consequence of this historical position is that in the UK we have a range of herbal products with MAs where in some cases the product currently is likely to come within the scope of Directive 2004/24/EC. There would be no legal basis to argue that products for which an MA was already held should be excluded from the implementation of Directive 2004/24/EC.

### (iii) Rationale for Government intervention

The MHRA has a requirement to ensure that medicines on the UK market comply with the requirements of medicines legislation. The rationale for action now is that this allows a planned, flexible programme.

#### **(iv) The proposal**

### **3. OPTIONS**

**Option 1: Do nothing.** This would entail leaving the position in which a number of older products have a marketing authorisation explicitly based on evidence of traditional usage whereas similar or even identical products now coming forward would receive THR

**Option 2: Instigate flexible programme to review herbal MAs leading to likely transfer of some products to THR status.** The main elements of flexibility proposed are:

- Allow companies with non marketed herbal MAs to use the public health exemption in the “Sunset Clause” in cases where they are considering possible transfer of product to THR status
- Allow companies until 2011 to put forward outline plans for the future of their herbal MAs, with opportunity for MHRA feedback and dialogue as necessary; with a further subsequent period to put in THR applications
- Instigate simplified arrangements for applying for THRs where company has an existing herbal MA which can be regarded as a “corresponding product”
- Allow companies entering the transfer process to take advantage of the greater flexibility of the THR scheme to make adjustments to the products
- Fees would not be charged for products undergoing the transfer providing the THR can be regarded as based on a “corresponding product” for which the company holds an MA and the relevant MA is cancelled/withdrawn at an agreed point in the transfer

**Option 3: As for 2 but without the specific benefits for companies**

- A tighter timetable would be required with all applications to be submitted by around 2010
- A full THR application would be required
- Fees would be charged for the THR application.

### **4. COSTS AND BENEFITS**

#### **(i) Sectors and groups affected**

The group most affected would be manufacturers of herbal medicines; in addition those wholesalers and retailers who market significant numbers of herbal medicines. Consumers would be affected to the extent that there were changes in the numbers of regulated products available and/ or information about regulated products.

The total number of products potentially affected by the review – at least as a starting number – is likely to be around 500. However, in practice the numbers affected in any substantive way are expected to reduce substantially in view of the significant number of herbal products with an MA which are reported to be not currently marketed (well over 200). Whilst perhaps a modest proportion of non marketed herbal MAs may find a new viability under the THR scheme it is likely that a considerable number of others will not and will not therefore require any significant consideration. Likewise, there will be some herbal MAs, number presently unknown, where it will be readily agreed that there is no issue with their continuing MA status. There is a considerable range in the extent to which individual companies may be affected. There are around a dozen or so companies with 10 or more herbal MAs, (in one case over 100). There is also a larger number of companies with only one or two herbal MAs. The total number of companies holding MAs for any herbal products may have been as high as around 50. However, consolidation in the market, both as regards products and companies, which has taken place over and number of years and which continues, suggests the current figure is considerably lower.

#### **Equality impact assessment/Specific impact tests**

The proposals would have no discernable effect on any of the following issues: legal aid, sustainability, carbon assessment or other environmental issues, race equality, disability equality, gender equality, human rights, or rural issues. Overall, the proposals would not affect any population group disproportionately.

## **(ii) Analysis of costs and benefits**

### **Benefits**

#### **Option 1**

- Would mean minimum change in the short term

#### **Option 2**

- Would progressively remove an area of overt legal risk and give companies greater certainty about the future of their products
- Would provide greater clarity for consumers. The Government's expert independent advisory body, the Herbal Medicines Advisory Committee (HMAC), has advised that it would be clearer for consumers if those herbal medicines based on efficacy and those based on traditional use were clearly allocated to the correct, distinct regulatory categories
- Would enable more effective communications about the regulated herbal medicines market by the regulator, by individual companies and by other interested parties to the benefit of consumers and business
- Would allow a measured programme of action, incorporating pragmatic features for companies and allowing them to plan ahead with a significant degree of discretion over timetable
- Could enable companies to "reactivate" the commercial value of some herbal MA products where products would benefit from updating or simplification but are currently unable to achieve this within MA structure on account of difficulties over efficacy
- If overall, say, 200 products transfer to THR status the total savings to companies from not requiring a fee for the transfer would be £20,000 for each £100 that the fee would otherwise have been

#### **Option 3**

- As for Option 2 in terms of reducing legal risk and ensuring clarity in the market place and would achieve these benefits more rapidly

### **Costs**

#### **Option 1**

- No short term costs
- Medium and longer term risks of industry incurring costs as result of consequences of a challenge as to why herbal medicines overtly based on traditional use remained in the MA category despite falling within the scope of European Directive 2004/24/EC on traditional herbal medicinal products; potentially the consequence could be a requirement to resolve the position much more rapidly than proposed under Option 2 and with few if any of the benefits linked to that programme. (Illustrative information from companies was invited on the nature and extent of costs if the review/transfer programme had to be carried out to a tight timetable at short notice; no specific suggestions were received in response – possibly reflecting the fact that most responses supported or accepted the case for instigating the programme now)
- Risk to MHRA service levels to industry in the event of having to undertake a programme in unplanned way at short notice

#### **Option 2**

- No costs over those of normal compliance with legislative requirements (eg maintaining quality dossiers and product information) given that industry would be given ample time to plan

### Option 3

- Cost to companies of THR applications. If overall, say, 200 products transfer to THR status and no concessions were made on standard THR fees the total cost to companies could be in the order of £400,000. (However, it is more realistic to assume that a modified fee would be proposed reflecting the fact that the company held an existing MA and so the figure might more realistically be adjusted to somewhere in the order of £100,000 to £200,000.)
- There would be a further cost to companies from at least some of them having to undertake a significant programme of work within a condensed period rather than planned over a longer timescale. (Illustrative information from companies was invited on the nature and extent of costs if the review/transfer programme had to be carried out to a tight timetable at short notice. No specific suggestions were received in response, possibly reflecting the fact that that this was neither MHRA's favoured option and nor was it supported in consultation).

### Costs to public health budgets

Nil. At the margins there may be modest, unquantifiable savings from Options 2 and 3 as the proposals are likely to lead to an increase in the viability of some products that had become of limited commercial value eg in view of the difficulty of getting the MA varied. A more robust market in regulated OTC herbal medicines should mean at the margins, and with suitable publicity, consumers will have a lower propensity to source products from unreliable sources, eg unregulated products on the internet. Such products can pose a risk to public health either through lack of reliable information about safe usage of the product, or in certain cases through the inclusion of dangerous or illegal ingredients. These issues potentially can lead to greater call on the NHS.

## 5. CONSULTATION WITH SMALL BUSINESS: THE SMALL FIRMS' IMPACT TEST

The MHRA has conducted a written consultation as well as having dialogue with a range of companies affected, including small companies, companies with a large number of products affected, and a company with a large workload on bringing unlicensed s12(2) products into the THR scheme. Feedback both from written consultation and dialogue has been positive, with the preferred approach (Option 2) seen as being realistic and pragmatic, not least as regards the timetable. The MHRA has also received feedback from a number of companies, including SMEs, that the favoured Option offers useful flexibility and some benefits for companies, which they intend to explore. Several companies have specifically indicated that they were expecting an initiative of this kind and recognised the need for it. The British Herbal Medicine Association has been unanimous in recommending that its members use the process to transfer herbal MAs to THRs in appropriate cases and has welcomed the MHRA's approach towards smoothing the regulatory path for companies towards 2011.

The Proprietary Association of Great Britain (PAGB) has been less supportive of the proposals but nonetheless says that its members are willing to work with the MHRA on this issue. It has queried the need for the review. The PAGB doubts that the proposals comply with the better regulation agenda and with Code of Practice for Regulators, particularly in that clear risk has not been demonstrated. More specifically, the PAGB notes that its members with successful, actively marketed products with a herbal MA are concerned lest the MHRA will use the opportunity of the review to require changes in indications. PAGB also suggests that if products are simplified during the transfer process this will reduce product differentiation and could adversely affect marketing possibilities. The Herbal Forum says that initially there was a mixed view but now the majority of Forum members while not necessarily welcoming the proposals are prepared to accept them.

In response to these comments the MHRA notes that the situation here is distinctive in that Directive 2004/24/EC was specifically introduced to provide a suitable regulatory home for those traditional herbal medicines where it was difficult to demonstrate efficacy – irrespective of whether they were currently within regulation. To allow herbal medicines to retain an MA indefinitely notwithstanding the point that the product is explicitly based on evidence of traditional use rather than demonstrated efficacy carries an obvious legal risk in relation to non compliance with Directive 2004/24/EC: there is no legal basis for arguing that Directive 2004/24/EC does not apply to certain products, simply because they had previously had a marketing authorisation. To allow the current situation to persist clearly risks an

outcome that could place certain companies as well as the MHRA under heavy pressure to take action on a large number of products over a short period. The MHRA considers that it would be short sighted for the Agency to ignore this risk.

Moreover, the MHRA is also aware that at least several other Member States, having adopted various national approaches to granting of herbal licences on the basis of traditional use, are also now reviewing these products.

The MHRA fully accepts the advice of the independent expert advisory body, HMAc, that it would be beneficial for consumers if products were correctly assigned to the appropriate regulatory category.

The MHRA has responded to the concerns as to whether the Agency will use the opportunity of the review to require changes in indications against the wishes of the company by clarifying that it cannot rule out the possibility of proposing changes in occasional instances, notably in the light of HMPC monographs or advice from HMAc. In practice it may well be that companies themselves wish to propose modifications to claims that are perceived as vague or unclear to the consumer.

The possibilities of simplifying or updating some products during the transfer process represent an option for companies – there is no compulsion about the options for reducing the number of active ingredients, (other than in the event that there were a specific safety concern). It is clear from responses to the consultation that some companies wish to take up these possibilities.

Several respondents wished to elongate the timetable further at the point MHRA reaches agreement with companies on their provisional plans (ie to allow longer for submission of applications). However, it may be that these comments were based on the assumption that the MHRA would necessarily quickly agree a company's *whole* provisional plan at once. In practice, particularly where a company has a large number of products for consideration, it may be more realistic for MHRA to reach agreement with the company in several stages. On this basis, the MHRA considers that the original proposed timetable was reasonable.

Two other main concerns were raised in consultation, including by trade associations. First, where a product was transferred to THR status, would MHRA require further expensive user testing of product information. The MHRA has indicated that it does not envisage that there would normally be a need for repeat user testing as a result of a transfer to THR status. A second, more indirect, concern was whether it would in practice be possible to advertise THR products; if this was not the case transfer to THR status could adversely affect marketing of products. The MHRA is clear that the legislation envisages responsible advertising of THRs, and indeed sets out certain regulatory requirements. The MHRA is working with other advertising regulatory bodies to produce guidance specifically on THRs.

It was also suggested by several respondents that MHRA should seek to co-ordinate its action on this review with other EU Member States. The MHRA does not consider this to be feasible as history, current circumstances and priorities vary greatly between Member States.

One other suggestion was that the MHRA should take a more directive approach to the review in determining the timing of review of individual products in accordance with specific factors (risk assessment, emergence of HMPC monographs). The MHRA considers this type of approach would be overly burdensome for some individual companies. The position of individual companies varies greatly (eg numbers of herbal MA products affected, whether company also has s12(2) products) and the consultation and dialogue with individual companies has indicated considerable support for the flexible approach adopted in the original proposals. Clearly, the MHRA retains the ability to respond at any time where specific risks are identified affecting regulated products.

Overall, the MHRA believes that the proposals are fully in line with better regulation principles – and that this point is implicitly recognised in the responses of most recipients. In particular, a proportionate and targeted approach has been taken to unravelling a complex historic problem offering considerable flexibility for companies most affected; the outcome should be much greater consistency in regulation, and increased transparency for the public and for the sector linked to a sound starting point – that products should be clearly allocated to the appropriate regulatory category.

## **6. COMPETITION ASSESSMENT**

On the basis of the competition filter there is no requirement for a competition assessment. The principle factor is that, even with some consolidation in recent years, there are some dozens of companies operating in the herbal medicines market, with no individual company having a dominant market position and this position is expected to continue.

By far the main impact of the Directive on traditional herbal medicinal products as regards competition is to tackle the previously unfair advantage enjoyed by manufacturers in the unlicensed sector (particularly the less responsible ones) over those in the licensed sector. The early experience of the operation of the THR scheme is that it is leading to some rationalisation in the market – both of products and companies. However, 17 companies have already made applications for THRs indicating the likelihood of continuing robust competition in the market.

The effect of Option 2 would be to achieve a level playing field between companies with MAs and those with THRs (there will be some overlap between the companies). Without resolution of the issue, as the THR scheme becomes increasingly embedded and well known, the fact that herbal medicines based on traditional use were split between two regulatory categories would increasingly serve to confuse and hinder understanding of regulation, creating unnecessary imperfections in the market.

## **7. ENFORCEMENT, SANCTIONS AND MONITORING**

The MHRA is responsible for enforcement of medicines legislation. The MHRA considers, on present feedback from industry, that the progress of the programme particularly in the early years will require monitoring rather than active enforcement against companies' wishes. The Agency expects that a number of companies will see specific advantages in transferring products to THR status, while others will at least consider it as reasonable to clarify the future regulatory status of their products. In the event that there is any evidence that some companies are wishing to stand aside from the review indefinitely, the MHRA will consider the need for specific arrangements, for review of evidence of efficacy where the Agency considers that there may be herbal products with an MA without adequate evidence of efficacy. There is an ongoing requirement on MHRA to ensure that products comply with regulatory requirements.

The overall review process should ultimately help with compliance, by ensuring that product information for regulated herbal products is fully brought up to a good current baseline.

## **8. IMPLEMENTATION AND DELIVERY PLAN**

The plan will be launched with the issue of guidance. The progress of implementation and delivery can be readily monitored, initially through informal feedback from companies about their intentions. Subsequently it will be possible to monitor how many companies have submitted plans, covering how many products; with how many companies covering how many products have plans been agreed; and how many THR applications have been made and subsequently granted through the process.

One area for particular monitoring is the extent to which companies wish to make changes to the composition of the product when transferring a herbal MA to THR status. In the event that there is a significant workload arising from changes proposed to a wide range of products during transfer the MHRA may bring forward subsequent proposals for a fee relating to the category of THR applications in cases where adjustments are made to the composition of the product as part of the transfer process.

The PAGB had raised the issue of whether implementation in relation to simplified applications could be pursued through an industry self certification approach, (characteristic of BROMI – Better Regulation of Medicines Initiative). The MHRA envisages that the simplest form of transfer (ie where no changes are proposed to the formulation of the product or its indications) would be amenable to a BROMI – style approach in which the application would be accompanied by a checklist. Moreover, where companies have a number of transfer applications it should be possible to tailor the amount of scrutiny required in the light of the quality of the initial applications from the company. In any case, the MHRA will look to contain the workload for both companies and the Agency – for example, if MHRA was aware that the issue of a relevant monograph from the Herbal Medicinal Products Committee was expected the Agency could suggest that a company might wish to defer making its THR application pending that publication.

## **9. POST IMPLEMENTATION REVIEW**

Review of progress during implementation is envisaged 6 monthly, or more often if emerging problems are identified. Subsequently the MHRA will in particular wish to review the overall experience in order to assess whether its judgement is correct that the benefits and flexibilities offered to companies under Option 2 will allow the programme to proceed in a measured, manageable way ultimately with minimal, if any, need for compulsion. This more substantive review, by 2012 at the latest, will indicate whether the programme is on track to deliver the key benefit of clarity arising from progressive allocation of products to correct regulatory category. It is not the explicit purpose of the review to achieve revival of some non

marketed herbal MAs. Nonetheless, this is a possible benefit for some companies and by the time of a review 2012 it should be realistic to ask companies who have taken up this opportunity to estimate any financial benefits.

## **10. SUMMARY AND RECOMMENDATION**

**Option 2 is the recommended option. The MHRA believes that this approach will achieve the desired objective in minimising an obvious legal risk and bringing greater clarity for consumers. The proposed programme should include sufficient flexibility to enable a smooth transition over a number of years to a position in which regulated herbal medicines are in the appropriate regulatory category.**

**In contrast, MHRA believes Option 1 carries a significant risk of generating a handling crisis downstream both for some individual companies and for MHRA. Option 1 would also perpetuate confusion in the marketplace. Option 3 appears unduly onerous for companies.**

## Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

**Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.**

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes	
Small Firms Impact Test	Yes	
Legal Aid	Yes	
Sustainable Development	Yes	
Carbon Assessment	Yes	
Other Environment	Yes	
Health Impact Assessment	Yes	
Race Equality	Yes	
Disability Equality	Yes	
Gender Equality	Yes	
Human Rights	Yes	
Rural Proofing	Yes	

