Title: MHRA - Fees legislation 2012 **IA No:** 4025 **Lead department or agency:** MHRA **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 02/02/2012 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Tracy Murray 020 3080 6329 or Caroline Brennan 020 3080 6525

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£3.64m	£0.11m	-£0.11m	No	NA

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

The MHRA protects public health by regulating the UK medicines market. Intervention is necessary because patients can not be expected to determine for themselves how safe and efficacious medicines are. This regulatory function is fully funded by the fees charged. These fees are reviewed annually and the associated regulations are revoked and remade as necessary. Government intervention is now necessary to ensure that the fees reflect the true costs of MHRA's regulatory functions, and to simplify the currently confusing array of fees. Only Government can act to bring about these changes through legislation.

What are the policy objectives and the intended effects?

Produce up-to-date and fit-for-purpose legislation that is simple to use.
Ensuring that the Agency is adequately funded to fulfil its responsibilities for public health protection.
Ensuring that fee levels reflect fairly the costs related to that activity.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

0. Do nothing.
1. Targeted reductions and simplification of systems.
Option 1 is preferred on the grounds that this year's fee setting round proposes a package of fee reductions and simplifications. This will be in compliance with Treasury guidance and will save administrative costs to both industry and the MHRA.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 03/2013

Does implementation go beyond minimum EU requirements?			N/A			
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes	
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** 0		**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Earl Howe Date: 15/02/2012

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2009	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 3.64

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	**0**		**0**	**0**

Description and scale of key monetised costs by 'main affected groups'

Part of these measures involve transfers between MHRA and firms that pay annual to MHRA. Some of these transfers are from MHRA to foreign firms, which could constitute a loss to the UK. However, for reasons that are explained in the "Evidence Base" section, the transfers would be the same in both the "do nothing" option and option 1, and hence cancel each other out. The incremental cost of these measures is therefore zero.

Other key non-monetised costs by 'main affected groups'

None

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0.42	**3.64**

Description and scale of key monetised benefits by 'main affected groups'

There are three types of economic benefit. The cost-saving from avoiding the transaction costs of returning money to firms (£0.24 million annually), admin cost savings to UK businesses from having to deal with a significantly less complicated fees regime (£0.11 million annually), and the counterpart admin savings to UK government (MHRA) (£0.07 million annually)

Other key non-monetised benefits by 'main affected groups'

None

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There are no significant risks associated with this simple intervention. The most significant assumption concerns what happens to the surplus accumulated under the "do nothing" option. We have assumed that this surplus is returned to the firms that contributed it.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:						In scope of OIOO?	Measure qualifies as
Costs:	0	**Benefits:**	0.11	**Net:**	0.11	No	NA

Evidence Base (for summary sheets)

Section A. Problem under consideration

Government intervenes in medicines safety in order to protect the public by providing an independent assessment of whether medicines which are to be put on the UK market are safe, of good quality and efficacious. This is necessary because patients can not be expected to determine for themselves how safe and efficacious medicines are (a market failure caused by information asymmetry). Government regulation of medicines formally came into being with the introduction of the Medicines Act 1968 in response to Thalidomide. Regulatory schemes, such as licensing, authorisation and registration, applied to the private sector gives patients confidence that adequate standards of safety are being met.
The Agency also has a role in supporting innovation and enabling businesses to prosper, through handling routine regulatory processes promptly and efficiently.

The MHRA was established as a Government Trading Fund and, as such, is fully funded for its medicines regulatory function by fees in connection with the manufacture, sale and supply of medicines. The fees charged by the MHRA are monitored and reviewed annually to ensure, as far as possible, that the fees charged for a particular service reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges. Under the terms of the Trading Funds Acts, the MHRA has a financial objective to break even and to set fee levels to achieve this, after taking account of HM Treasury's requirement to earn 3.5% return on capital employed in real terms.

The government has a duty to ensure that its interventions are conducted as efficiently as possible. Over the last few years, MHRA has become more efficient in the way it operates, by working closely with industry to set out guidelines and strict timelines for collection, analysis and follow-up data for each product so it now achieves deadlines. The MHRA is now in a position to pass on those efficiencies to industry. At the same time, the MHRA has reviewed its fees structure in order to reduce some of the complexities which are either no longer justifiable (such as differential fees for similar applications which have been submitted in different formats) or which add administrative burden to both the Agency and the industry (such as the tiered system of charging some specific annual fees).

The specific problems we are trying to resolve are:

- ensuring that we charge the right price for the work done and not overcharge the industry - this has arisen because in some instances, we introduced a differential fee for certain applications made through an electronic portal compared to those received using other electronic means. We consider that the price should be the same for both as there is no difference in the amount of work required to process these cases. In addition, we have reviewed the fees for other specific applications and consider that one or two are charged at a higher rate than now required due to efficiencies made within MHRA processes;
- the current structure causes additional administrative burden for both the Agency and the industry in time taken to resolve queries each year e.g. a medium sized company with 300 general sale product licences takes on average 6 weeks to validate the fee they need to pay for each licence which is currently based on the turnover of each product (3 different fees). The invoice will then take the MHRA a week to process and agree each fee based on the evidence given by the company. Under the simplified system this will significantly reduce as the company will pay a set fee for each 300 licences irrelevant of turnover – all they will need to validate is whether the licence is still ‘live’. The MHRA will process this invoice within one day once conformation from the company has been received.

B. What are the policy objectives and intended effects?

The proposal for 2012/2013 is to continue to achieve full cost recovery of the work undertaken, whilst targeting areas for reduction where efficiency measures have been put in place by the agency, to ensure fees are directly related to cost. Simplification of regulation is also a driver for the Agency – making it easier for industry to understand the legislation, and less time consuming to explain complex systems to individual companies thus reducing a certain amount of burden on both the Agency and the industry.

The Agency also intends that, through the implementation of these fee proposals, it will support its broader objectives and priorities, including:

- Ensuring that the Agency is adequately funded to fulfil its responsibilities for public health protection;
- Improving efficiency and promptness in the handling of licence applications and variations;
- Ensuring that fee levels reflect fairly the costs related to that activity.

C. What policy options have been considered, including any alternatives to regulation?

3. Options

3.1 Two options for the main proposals have been identified:

Option 0: Do nothing options i.e. make no changes to fees which would mean leave the legislation as it currently is.

Option 1: Targeted decreases and simplification –

Option 1 is designed to ensure that MHRA's fees revenue equals its costs, thereby avoiding the situation of future surpluses accumulating. Option 1 is also a simplifying measure which is intended to reduce net burdens on business. Legislative simplification is an established form of better regulation initiative.

	Benefits, Costs and Transfers.	**Sectors likely to be affected by the proposal**
Change 1 A 10% fee reduction for RMS DCP* for 2012/13 eCTD** variants being reduced by 5% to align with their non-eCTD equivalents. (**RMS DCP is a type of Marketing Authorisation application where a Member State wishes to market their product in more than one country* ***eCTD are specific types of electronic applications for which there*	To bring the UK in line with other EU countries fees and with the Agency's implementation of measures of efficiency in processing marketing authorisations. Decentralised Procedures (DCP) where the UK is the Reference Member State (RMS) income was worth £16.3m to the Agency in 2010/11. Transfer to industry in region of £1.6m per year – this is calculated : Total volume (based on 2010/11) = 646 Fee total = 16,320,280 Transfer to industry = 1,632,028	All industry who hold Marketing Authorisations

<table>
<tr><td>was a different fee set)</td><td></td><td></td></tr>
<tr><td>Change 2
The removal of the eCTD fee differentials from all applications by reducing non eCTD fees to the eCTD equivalent, a fee reduction of 5% for the fees affected.</td><td>This initiative would simplify the fee regime; a total of 56 fees would be removed from the Regulations.
Based on volumes for 2010/11:
Applications = 2,679 of which are eCTD = 305
Variations = 15,409 of which are eCTD = 743
Total = 18,088 = 1048
% overall of eCTD applications = 6%
Transfer from MHRA to industry, if volumes remained the same, would be £1.8m
<table>
<tr><td>2010</td><td>Applications</td><td>Variations</td><td>Total</td></tr>
<tr><td>Non-eCTD income</td><td>£26.7m</td><td>£9.2m</td><td>£35.9m</td></tr>
<tr><td>Transfers from MHRA to industry if reduce fees to eCTD levels</td><td>£1.3m</td><td>£0.5m</td><td>£1.8m</td></tr>
<tr><td>Reduction in fee types</td><td>24</td><td>32</td><td>56</td></tr>
</table></td><td>All industry who hold Marketing Authorisations</td></tr>
</table>

<table>
<tr><td>Change 3
Move to a single periodic (annual) fee per parallel import licence held of £300.</td><td>Removal of a tiered system comprising of 12 fees based on a combination of turnover and legal status and number of UK reference products.
Periodic (annual) fees collected from Parallel Import Licences are c£5m per annum. There is currently significant time spent in administrative exchanges between companies and the Agency to finally determine the correct fee payable.
This would represent a significant simplification and there would be less scope for fee dispute thus reducing some administration costs for some companies (as well as the Agency)
Twelve fees would be reduced to one.
Of the total 61 companies who currently pay the tiered system of periodic fees:
<table>
<tr><td>Fee</td><td>£300</td></tr>
<tr><td>Number of companies who pay less</td><td>36</td></tr>
<tr><td>Fee reduction</td><td>£2.2m</td></tr>
<tr><td>Number of companies who pay more</td><td>20</td></tr>
<tr><td>Fee increase</td><td>£0.6m</td></tr>
<tr><td>Net transfer from MHRA to industry</td><td>£1.6m</td></tr>
<tr><td>Estimated savings in administrative time
Agency is likely to save approximately
£17,300 in administrative costs (3 months x 2 full-time EO staff cost, working April – June on invoice queries from companies resulting from the annual fee request
Industry saving: At present it is estimated that it takes 4-5 days to verify all entries on invoices for PI companies, once</td><td>£17,300
£17,400</td></tr>
</table></td></tr>
</table>

	the simplification has taken place this should reduce to 2-3 days. Therefore 2 day saving @ national average staff cost (£143 per day) x 61 (total companies) = £17,400 **(representatives of the industry including some representing small operators have commented that the assumptions included here are reasonable)**.	

Change 4 Move to a system of 3 periodic (annual) fees for non parallel import product licences, with the lower fee set at £300.	There are currently potentially 12 different annual fees payable by mainstream medicines licence holders. Products with the legal status of Pharmacy (P), General Sale List (GSL) and None make up c3, 000 payments (15% of all payments) but only contributes c6% of the MHRAs overall revenues (£1-2 m). Analysis of these companies shows if the fees were set at £300 instead of the current tiered system of between £1,038 and £93 of the current 691 companies:		All industry who hold a licence/ marketing authorisation
	3 Fee System		
	Number of companies who pay less	395	
	Fee reduction	£1.2m	
	Number of companies who pay more	37	
	Total additional fees	<£0.1m	
	Net transfer from MHRA to industry	£1.1m	
	Admin Savings	£1.1m	
	Agency is likely to save approximately £34,700 in administrative costs (12 months x full-time EO staff cost working from April on invoice queries from companies resulting from the annual fee request	£34,700	
	Industry is likely to save approximately £181,000 based on admin costs (30 mins per payment (c19,000) @ £19.00 per hour (national average staff cost) – checking whether still live, which classification fee should be paid **(representatives of the industry including some representing small operators have commented that the assumptions included here are reasonable)**.	£181,000	

Change 5 Move to a system of a single fee of £75 for all of the periodic (annual) fees for herbal and homeopathic providers, except for the Simplified	This would reduce 6 sets of fees down to 1. There are c1,000 payments made in respect of these products, but only contribute to .1m to MHRA revenue. Using current volumes (2010-11) the breakdown of current payments: 402 @ £74 = £29,748 403@ £113 = £45,539 80 @ £81 = £6,480 Total = £81,767	All herbal/ homeopathic providers

Homeopathic Registration periodic fee, which would be removed.	Costs to Agency An admin saving to MHRA for one Administrative Officer (AO) (881 x one hour each company = £12,334) based on £18.00 per hour. Saving to industry 483 companies will pay less = £15,794 402 companies will pay £1 more = £402 Therefore net saving to industry = £15,392 <u>Simplified Homeopathic Registrations:</u> There are c181 companies who pay the £24.00 per year for a simplified homeopathic registration, total fee payments = £4,344 per annum. These companies will pay nothing in future. Cost/ Saving to Agency: Working on the assumption that it will take an AO two hours per year (£18 per hour) to process, maintain a data base and chase invoices = £6,490 per annum. Saving to industry is £4,344 plus one hour processing time @ £19 per hour staff cost (£3,445) = £7,789 per annum. <u>SUMMARY</u> Transfer from MHRA to industry = £20,138 Industry (homeopathic) admin savings = £3,445 Transfer from industry to MHRA = £402 MHRA admin saving = £22,286	
Transfer from MHRA to industry	**£6.8m**	
Transfer from industry to MHRA	**£0.7m**	
Net transfer from MHRA to industry	**£6.1m**	
Total admin savings for industry	**£0.1m**	
Total admin savings for MHRA	**£0.1m**	

D. Analytical assumptions

We assume that the volume of work which comes to the MHRA remains constant at the previous year's level and is not affected by the change in fee levels.

We have used the standard ten year appraisal period and HMT's standard 3.5% social discount rate.

Under the "do nothing" option, assumptions about what happens to the MHRA financial surplus are crucial in determining the balance of costs and benefits of Option 1. We believe that the surplus would most likely be returned to the firms that contributed it. We believe that possible alternative uses of the

surplus would prove unacceptable. For instance, the surplus could be transferred to the Department of Health, MHRA's principal Department. However, this would most likely prove politically unacceptable because the firms that contributed the surplus could justifiably complain that they would be directly funding the nation's healthcare.

Alternatively, the surplus could be spent by MHRA. However, MHRA would have to invent creative ways of spending these windfall funds, which were not included in its original budget planning process. The social value of such spending would be questionable.

Finally, Treasury rules prevent departments and agencies from contributing money to the general exchequer.

Our assumption that surpluses are returned to firms under the "do nothing" option means that the same magnitudes of transfers occur in both the "do nothing" and "fees reduction" options. In this one respect, there is no difference between the two options.

Some of the transfers would be from the MHRA to foreign owned firms.

To distinguish between the impact of the simplifications on UK and non-UK businesses, we have assumed that the changes affect profitability, which in turn affects returns to capital. We are therefore using the proportion of UK shareholding in the affected businesses as the determinant of what comprises UK and non-UK interests. This approach has been cleared by BRE.

Unfortunately, as far as Marketing Authorisation Holders are concerned, we know little about the proportion of UK shareholding. The World Health Organisation estimated that in 1999 the UK had a 6% share by value in world pharmaceutical production[1]. Taking this figure as our midpoint, we have assumed a range of plus and minus 3% to reflect the substantial uncertainty we feel about the exact proportion[2].

We have assumed that all parallel importers, herbal and homeopathic firms are fully UK owned. "Change 4" requires us to make assumptions about what proportion of non-prescription only medicine (non-POM) marketing authorisation holders (MAHs) are UK owned. We have assumed that 80% of MHRA's 3,500 licence applicant companies deal in POMs (we have used the proportion of POM total fee payment volumes as a proxy for POM MAHs). We have applied our assumption of 3% to 9% of UK ownership to the non-POM MAHs (20% of 3,500 = 700). We have combined these assumptions with our assumption about 100% UK ownership for parallel importers (61 firms), herbal (61 firms) and homeopathic firms (61) to yield a UK ownership proportion of approximately 47% for "Change 4".

Financial gains to UK businesses and shareholders should be adjusted to reflect the social opportunity cost of these funds. If on average the beneficiaries of the funds (who, at least in the short run, are the company shareholders) are wealthier than the UK national average, then distributional weighting of less than one should be used to convert financial gains to economic (societal) gains (Annex 5 of Treasury Green Book 2003). Unfortunately we have insufficient information on share ownership in the affected firms and have therefore assumed a distributional weighting of 1.

We have assumed various staff costs for administration saving estimates. We have taken the national average wage as the basis for industry administration grade staff costs and added 30% to allow for non-salary staff costs. This yields an hourly cost of £19. For MHRA we have taken the relevant staff grade midpoint salary and added 30%. This yields an Administration Officer (AO) staff cost of £18 an hour, and a yearly Executive Officer (EO) staff cost of approximately £35,000, which converts to an hourly rate of £22.

Engagement with stakeholders

[1] http://apps.who.int/medicinedocs/en/d/Js6160e/3.html#Js6160e.3 The basis for this calculation is not clear and it might not be based on UK shareholding.

[2] Arguable we should adjust this figure for the marginal utility of income for shareholders (generally wealthy individuals) and for the non-socially-productive industry practice of spending money on rent seeking. However. given that in this case we are considering a transfer from government to industry, making these adjustments would imply that money in government hands is more valuable than in investors hands. Given the Coalition's current policies for boosting growth, we do not feel it is appropriate to make this assumption.

During the review of our fees policy, we have actively engaged with industry trade bodies and officials across relevant Government Departments through:

- Policy Group meetings with representation from key stakeholders within the organisation (monthly basis).
- 2 industry policy roundtables held in late spring 2011 (where information concerning small businesses was specifically requested).
- A series of cross-departmental meetings with relevant other Government Departments (DH, Treasury and BIS).

Response from consultation exercise

A formal consultation exercise took place on the proposals. During the consultation period, we continued to engage with stakeholders through easy-read resources, intermediary support, discussions via email and telephone focusing on the key questions in the main policy consultation.

The consultation closed on 31 January 2012. A total of 8 responses were received – all supported the proposals. The main themes of the responses were:

- support for the MHRA's role in safeguarding public health and to be fully funded for its medicines regulatory function by fees;
- welcomed the opportunity to engage in the consultation process including the opportunity provided for early discussions on the proposals and the transparency of the fee setting process;
- welcomed the proposed simplification measures to reduce administrative burden particularly on SMEs;
- welcomed the removal of a number of fees which would assist in reducing cost and time to industry;
- welcomed the proposed simplification of periodic fees and a reduction in fees charged under the decentralised procedure where MHRA is the reference Member State; and
- welcomed the proposed freeze in other fees.

Some of the industry trade associations including those representing small operators commented that the assumptions made in the IA in relation to savings to industry (including admin savings) are reasonable.

E. Baseline: The do nothing option (Option 0)

This option would:

- Keep 69 specific fee prices ranging over a number of different types of application which are complex and difficult for industry the agency to administer;
- Fees would not reflect the true costs of work related to that activity – over-pricing could occur in the future - not compliant with the Trading Fund legislation.

Note that we have assumed that the surpluses generated under the "do nothing" option are returned to the firms that contributed them. This assumption is discussed in Section D "Analytical Assumptions". In returning the surplus, MHRA would incur transaction costs. These transactions would not be necessary under Option 1. These costs have been estimated in the next section and counted as cost-savings under Option 1.

F. Costs and benefits of Option 1

MHRA staff time has already been spent on developing and consulting on Option 1. However, these costs are sunk and therefore not counted in this analysis.

<u>Sectors and groups affected</u>

All sectors of the pharmaceutical industry, including herbal and homeopathic sectors involved in the manufacture, sale and wholesale of medicinal products for human use (around 3,500 organisations and companies in all). These Regulations also affect academia where medical research and clinical trials are carried out, and NHS organisations that manufacture products.

It is not possible to identify a "typical" business. Businesses range from small "one-man-band" wholesale dealers, NHS Trusts and hospitals, academic research establishments, up to multi-billion pound international manufacturing businesses.

We believe that there are very few UK small businesses (firms with fewer than 50 employees) affected by the proposed changes. Of MHRA's 3,500 customers, only 10 have applied for small business status.

Two of these are herbal companies. During the consultation, we re-checked historical data to ensure that our records were correct and presented an accurate picture of small business numbers which they do. We also asked industry representative bodies (both in face to face meetings we held to discuss the changes, and by email) to give any further information they held concerning UK small businesses and if they would be affected by the proposed changes. The Ethical Medicines Industry Group (the pharmaceutical trade association that represents the interests of over 160 small to medium sized companies (SMEs) based in the UK felt that the simplification of some fees would help reduce the administrative burden of SMEs. We have also had 2 positive responses from individual companies on how they believe the changes will simplify their administration processes and understanding of the new legislation.

We are not aware of any micro-businesses that will be affected by these changes following the consultation process.

Economic Costs

As noted in the "Analytical Assumptions" section there are no incremental UK costs associated with transfers from MHRA to foreign owned firms. This is because we have assumed that the same transfers occur in both the "do nothing" option and Option 1.

There are no other incremental costs associated with Option 1.

Economic Benefits

This section presents three types of economic benefit: cost-savings from not having bear the transaction costs of returning surplus money to firms (necessary under the "do nothing" option), admin cost savings to UK businesses from having to deal with a significantly less complicated fees regime, and the counterpart admin savings to UK government (MHRA)

The assumptions underpinning our estimates of the industry and MHRA admin cost savings are described in the table in Section C.

Our estimates of the Option 1 MHRA transaction cost savings from not having to return surplus money to firms (which we assume would be necessary under the "do nothing" option) are presented below. The time taken for each type of transaction has been estimated on the basis of its complication.

	No. transactions	MHRA admin hours for refund	Rate per hour	Total cost
RMS DCP fee transactions	646	1	£22.41	£14,476
eCTD transactions	18,088	0.5	£22.41	£202,664
Parallel Import periodic fee transactions	61	0.5	£22.41	£683
Non-PI periodic fee transactions	432	1	£22.41	£9,681
Herbal and homeopath period fee transactions	885	1	£17.93	£15,867

Total	20,112			£243,371

A summary of the three types of benefits is presented in the table below.

	Annual Benefits (£ million)			
	Transaction cost savings	Industry admin cost savings	MHRA admin cost savings	**Total**
Change 1	0.01	0	0	**0**
Change 2	0.20	0	0	**0**
Change 3	0.00	0.02	0.02	**0.04**
Change 4	0.01	0.08	0.03	**0.13**
Change 5	0.02	0.00	0.02	**0.04**
Total	**0.24**	**0.11**	**0.07**	**0.42**

Present Value of UK Economic Costs and Benefits

The figures in the table below summarise the economic impacts on the UK in terms of transfers to and from oversees interests, and industry and government admin cost savings.

Year	0	1	2	3	4	5	6	7	8	9	Total
PV costs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PV benefits	0.42	0.41	0.39	0.38	0.37	0.36	0.34	0.33	0.32	0.31	3.64
PV net benefits	0.42	0.41	0.39	0.38	0.37	0.36	0.34	0.33	0.32	0.31	3.64

Note that costs and benefits start in the second quarter of 2012 (year 0)

Present value of Financial Costs and Benefits to UK Firms and Shareholders

The figures in the table below summarise the financial effects on UK businesses and shareholders in terms of transfers to and from MHRA, and admin cost savings.

Year	0	1	2	3	4	5	6	7	8	9	Total	Annualised
PV costs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PV benefits	0.11	0.10	0.10	0.09	0.09	0.09	0.09	0.08	0.08	0.08	0.91	0.11
PV net benefits	0.11	0.10	0.10	0.09	0.09	0.09	0.09	0.08	0.08	0.08	0.91	-0.11

Note that costs and benefits start in the second quarter of 2012 (year 0)

Key sensitivities and risks

There are no significant risks associated with this simple intervention.

The most significant assumption concerns what happens to the surplus accumulated under the “do nothing” option. In Section D “Analytical Assumptions”, we stated that the most likely use of the surplus funds would be to return them to the firms that contributed them. We also discussed other possible uses that we believe would prove unacceptable.

Specific impact tests

Economic

Competition assessment

MAHs include originator and generic manufacturers, who can further be divided into Prescription Only Medicine (POM), Pharmacy only (P) and over the counter medicine (OTC) manufacturers.

UK markets for originator POM medicines that contain innovative active substances are nation-wide (due to centralised pricing and cost-effectiveness arrangements), and experience strong dynamic but little static competition. Development of these medicines is always associated with high research and development costs.

UK markets for generic, off-patent POM medicines are nation-wide and experience static competition based on discounts given to medicines wholesalers.

Markets for originator and generic non-POM medicines are geographically local, are characterised by significant amounts of substitution, and experience both static and dynamic competition.

Markets for herbal and homeopathic medicines are geographically local, are characterised by significant amounts of substitution and experience some static competition based on price and marketing claims of the benefits of the competing products.

Markets for medicines parallel importing services are nationwide because of the national structure of the medicines wholesaling sector, which is the main customer for the parallel imports. Parallel importers compete with manufacturers by exploiting international price differentials created by the manufacturers. The services compete entirely on the basis of price.

Answering the competition assessment questions, we believe that the measures:

1. Will not directly limit the number or range of suppliers
2. Will not indirectly limit the number or range of suppliers.
3. Will not limit the ability of suppliers to compete.
4. Will not reduce suppliers' incentives to compete vigorously

Small firms impact test

MHRA records of the number of small firms that are affected by these changes suggest that the total is very small. Of MHRA's 3,500 applicants, only 10 have registered for small firm status.

Because the changes reduce admin costs (through reducing the complexity of the fees regime), their impact on small firms would be disproportionately beneficial – small firms often lack the resources to meet their administrative regulatory responsibilities.

Equality

An initial Equality Impact screening assessment has been carried out, which has shown that a full assessment is not required as the proposed policy has no disproportionate impact on race or other relevant equalities. The proposed policy will not have any disproportionate impact on rural populations, protected characteristics under the Equality Act 2010 of race, disability and gender, age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.

Wider Environmental Impact and Greenhouse Gases Tests

There are no potentially significant impacts on air quality, water quality and quantity, flood risk, biodiversity, landscape or noise arising from these proposals. This policy will have no impact on greenhouse gas emissions.

Social impacts

The proposals will not directly impact on health or wellbeing and will not result in health equalities.

Health and well being

We have considered the health impact screening questions and do not consider that this legislation will have a significant impact on any of the three questions. Medicines clearly have a fundamental role in the delivery of health and social care services but these regulations do not alter the current arrangements.

Human Rights

The preferred option will have no material impact on any of the 16 Convention rights referred to in s. 1 Human Rights Act 1998.

Justice system

Our option has no impact on Justice systems.

Rural Proofing

Our options have no significant impact on rural communities.

Sustainable development

The policies will have no impact upon sustainability and will not adversely affect future generations.