Title: Consolidation of UK medicines legislation **IA No:** 4018 **Lead department or agency:** Medicines and Healthcare Products Regulatory Agency **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 09/03/2012 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Daniel Markson - daniel.markson@mhra.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: AMBER

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**
£9.0m	£8.1m	-£0.9m	Yes	OUT

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

The medicines regulatory framework is complex and confusing. This creates three principal problems. First, it makes it harder for the MHRA to carry out better regulation initiatives. Second, costs to the private and public sectors of understanding and applying the law are much higher than necessary. Third, uncertainty about legal requirements can lead to wasteful legal proceedings.

Government intervention to change legislation is necessary because legal certainty is a public good. The free market lacks the incentives to supply public goods adequately. Only Government and Parliament can legislate. Industry bodies have also asked MHRA to address this problem.

What are the policy objectives and the intended effects?

Objective 1. Facilitating future better regulation initiatives, including reviews of policies embodied in the law.

Objective 2. Reduced private and public sector costs of understanding and applying the law.

Objective 3. Reduced litigation costs to the private and public sectors.

The intended effects are to safeguard public health in the most cost-effective and transparent manner, and to reduce regulatory burdens and thereby contribute to productivity and growth in the private and third sectors.

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

0. Do nothing. Continue to add to and amend the existing complicated legal framework.

1. Recast the legal framework and cut out redundant legislation to make the law easier to understand.

The MHRA previously considered the option of improving the legislative guidance to help users navigate more effectively through the complicated law. This option was rejected on the grounds that it does not meet the fundamental objective of facilitating future better regulation initiatives.

Option 1 is preferred on the grounds that it addresses the fundamental cause of the problems outlined above - the opaqueness of the regulatory framework. It is further justified on the basis that it provides a positive net present value, even without the inclusion of several significant unquantified benefits.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 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: ..... Date: 25 June 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: -£1.3	**High:** 19.4	**Best Estimate:** 9.0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	1.7		Optional	**Optional**
High	3.1		Optional	**Optional**
Best Estimate	2.4		0.002	**2.4**

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

The private sector faces estimated transition costs of between £1.3 million and £2.6 million, and no recurring annual costs. Public sector estimated transition costs are between £0.4 million and £0.5 million (of which £0.26 million are MHRA policy and legal costs). MHRA's annual recurring costs are expected to be £2,000 (PV £19,000).

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			0.2	**1.8**
High			2.8	**21.1**
Best Estimate	0		1.5	**11.5**

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

The private sector is expected to enjoy annual benefits of between £0.12 million and £2.65 million annually (PV £0.45 to £4.04 million). The public sector is estimated to benefit by £0.12 million annually (PV £0.91 million).

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

1. Public sector economies and efficiencies in future deregulation projects.
2. Reduction in cases where businesses over-comply to ensure they have met obligations under unclear regulations.
3. Reduced litigation cost for public and private sectors.

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

There are no key unmitigated risks.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.222	**Benefits:** 1.160	**Net:** 0.940	Yes	OUT

Evidence Base (for summary sheets)

A. What is the problem under consideration? Why is Government intervention necessary?

Medicines are a central part of healthcare in the UK. Medicines regulation provides the framework that underpins safe medicine use by professionals and the public, yet the law is complex and confusing. UK medicines legislation comprises the Medicines Act 1968, around 60 principal statutory instruments and around 130 amending statutory instruments, which reflect developments in pharmaceuticals, wholesale trade, regulatory practice and European harmonisation. The law has become fragmented and potentially impenetrable for users in the public, private and third sectors.

Furthermore, as law has accumulated, some legislation has become redundant and has fallen into disuse. Although no one is now bound by it, it nevertheless litters the legislative landscape and makes it harder for users to understand the law that currently applies.

Legal complexity has created three principal problems:

- The legislative structure hampers MHRA's efforts to improve the effectiveness, transparency and proportionality of its regulation, and to ensure its regulation reflects best practice. Identifying opportunities for burden reduction and ensuring that regulation is consistent across all the legislative framework are difficult, and errors can easily be made.

- Costs to the private and public sectors of trying to understand and apply the law are significantly higher than necessary. An illustration of this comes from practitioners in pharmaceutical law, who estimate that giving legal advice can take several times longer – and therefore cost several times more - than if there were a single, coherent set of regulations[1].

- Uncertainty about legal requirements can lead to wasteful legal proceedings and can, in the extreme, render the law incapable of enforcement.

These problems are becoming more acute over time, as the stock of medicines legislation grows. It is the Government's responsibility to resolve these problems; no-one else, other than Parliament, can legislate in this field.

The private sector provides up-to-date versions of the Medicines Act 1968 and the principal statutory instruments, incorporating the amendments made to them. It also provides an update service about new legislation. However, the providers of these services can only help industry to navigate through a complicated legal framework; they do not provide a single, simplified text; and subscription represents a cost for businesses. The underlying problem – the complicated framework – remains unaddressed. Industry bodies have asked MHRA to tackle this fundamental problem.

Moreover, legal certainty is a public good (if you can supply it to one person you can supply it to all people at no extra cost, and one person's consumption of it does not mean that there is less for others to consume). The free market will undersupply the good, because the private sector is unable to capture its full share of the social benefits of supplying the good to all who would benefit from consuming it.

B. What are the policy objectives and intended effects?

The goal is to simplify the structure of the law, improving its accessibility to industry, professionals and lay readers. This is a significant better regulation initiative that is consistent with the Government's principles of regulation. It will contribute to transparency, legal certainty and the rule of law, and reduce administrative and compliance burdens. This will make it easier for professionals to do their jobs and

[1] A pharmacy lawyer has given an example where drafting a letter of advice supported by reference to the legislation took 8 hours. If there had been a single set of Regulations the work might have been completed in about 2 hours.

simpler for industry to comply, and ultimately patients will benefit from a licensing system fit for the twenty-first century.

Specifically, MHRA aims to achieve the following objectives:

- Facilitated future better regulation initiatives, including reviews of the policies embodied in the legislation;
- Reduced private and public sector costs of understanding and applying the law;
- Reduced litigation costs to the private and public sectors.

MHRA does not expect the changes to have any adverse impact on public health.

The intended effects are:

- to safeguard public health in the most cost-effective and transparent manner
- to reduce burdens, and to contribute to productivity and growth in the private and third sectors.

Achieving the objectives is expected to contribute to the intended effects in two ways:

- Firstly and most importantly, legislative simplification will contribute to cost-effective public health and to growth by facilitating future better regulation initiatives. Although this could be achieved without simplifying the legal framework, these improvements can be introduced more quickly, will be more easily understood and will be less prone to legal mistakes if they are carried out within the context of a simplified legal framework.
- Secondly, the reduced costs of understanding and applying the law, and avoided costs of fruitless litigation, will allow the private and public sector to apply the cost savings to more productive uses. For the same reasons simplification will also reduce regulatory barriers to entry. MHRA does not, however, expect these direct benefits to be large in the context of the pharmaceuticals sector, and has therefore taken a proportionate approach to this final-stage impact assessment.

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

The MHRA has informally consulted on a number of previous occasions and has found widespread support for the proposal to consolidate the law.

The MHRA has also narrowed down the options along the way. It previously considered the option of rationalising and improving its legislative guidance, rather than the legislation itself. However, better guidance would not provide a platform for further better regulation initiatives. It would therefore not meet a key policy objective. In addition, it would not address the fundamental cause of the costs – the complicated legislative framework. By definition, improved guidance would also present less certainty than improved law itself. It would therefore be a second-best solution and inherently less beneficial than Option 1. For these reasons, the guidance option was considered inferior to Option 1, and was rejected.

Two options therefore remain.

Option 0. Do nothing: MHRA continues to add to and amend the existing legal framework in a piecemeal manner, as necessary.

Option 1. MHRA recasts the legal framework to make it easier to understand and to cut out redundant legislation. Thereafter, MHRA reconsolidates legislation periodically, and meanwhile maintains an up-to-

date informal consolidated text on its website. The Government proposes to bring together the 200[2] or so legislative instruments into one statutory instrument that sets out for the first time almost all of the regulatory requirements for medicines in a single text.[3] An explanation of how this consolidates existing law is at annex A, and a list of the redundant legislation that is being repealed is at annex B.

Option 1 can be seen as phase one in MHRA's regulatory excellence programme. Further initiatives will be introduced on the back of Option 1. Option 1 is a simplifying measure which is intended to reduce net burdens on business. Legislative simplification is an established form of better regulation initiative.[4]

Note that this is not (with certain minor exceptions, which are outlined in the consultation document) intended to be a change to policy. It is a simplification measure that will allow policy to be reconsidered in the future. Alternatives to regulation are therefore irrelevant in this context, although they will be considered during future reviews of the stock of regulation for which MHRA is responsible

D. Analytical assumptions

The appraisal period has been capped at 10 years. This is a conservative approach because we expect substantial benefits to continue well beyond this period.

The social discount rate is the Treasury recommended 3.5%.

A GDP deflator of 0.972 (sourced from the HM Treasury website) has been applied to all 2010 costs and benefits to base prices in 2009 values, in accordance with One-in, One-out procedures.

The public consultation returned 202 responses, of which 62 addressed issues directly relevant to this impact assessment. MHRA followed this up by contacting a further 10 organisations to fill in gaps in the evidence base.

The consultation and follow up revealed the following:

- We had under-estimated the time that firms spend understanding the legislation as it is currently drafted. This was particularly the case for medicines wholesalers. We had previously estimated that the costs to the private sector of understanding the regulations were between £0.64 million and £2.07 million. Our new estimate is between £0.63 million and £5.14 million.
- Our assumption that small pharmacy firms, homeopaths and herbalists rely on their representative bodies for regulatory advice proved correct.
- We had excluded Primary Care Trusts and Strategic Health Authorities from our estimates. This has now been corrected.
- We had under-estimated the cost of the staff time spent on regulatory matters. This was particularly the case with manufacturers, for whom we increased the rate from £25 to £65 per hour.
- We had under-estimated the costs of familiarisation and changing guidance by factor of between 2 and 3.
- We had substantially under-estimated the time savings to Manufacturers as a result of clearer regulations. Whereas we had previously assumed a 5% to 15% saving, consultation responses from several manufacturers and their representative bodies suggested the savings could be as much as 50%.

[2] Approx 60 principle SIs and 130 amending SIs

[3] We do not at present propose to consolidate (a) fees, a discrete and complex area of legislation which the MHRA intends to simplify and rationalise separately; (b) clinical trials, where there are ongoing negotiations at a European level about the introduction of a Directive that will require substantial changes to the regulation of clinical trials shortly; or (c) prohibition of substances, as there are insufficient legal powers to include these provisions in the consolidated regulations. When the legislation in relation to fees and clinical trials is more settled, the MHRA will explore consolidating it into the consolidated regulations. The consolidation does not cover pharmacies legislation, which is administered by the Department of Health. Part 4 of the Medicines Act 1968 (Pharmacies) will not be repealed and will still need to be read in conjunction with other pharmacies legislation.

[4] The European Commission, for example, frequently uses recasts/consolidations as part of its rolling simplification programme: http://ec.europa.eu/governance/better_regulation/codif_recast_en.htm

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

Although the "do nothing" option implies no change and therefore no incremental costs and benefits, MHRA has estimated the current costs to the economy of understanding the current complicated regulations, and of seeking legal advice. This approach provides the basis for estimating the benefits (in the form of cost savings) to the private and public sectors reported in Section F.

Current private sector costs of understanding regulations

Manufacturers of pharmaceuticals, medicinal chemicals and botanical products (SIC 244)

BIS statistics suggest that there are 385 businesses in this sector (of which 230 are micro and 65 medium sized). MHRA has assumed that between 15 and 180 hours[5] a year are spent by each firm understanding the current regulations. The salary cost is assumed to be £50 per hour[6], to which we have added 30% to account for non-salary staff costs. The total staff cost is therefore £65 per hour. These assumptions yield annual costs ranging from £0.39 million to £4.50 million.

Pharmaceutical industry representative bodies

On the basis of feedback from industry representative bodies, MHRA has gathered that pharmaceutical industry firms do not consult their representative bodies for significant amounts of legal advice and hence these bodies' annual costs of consulting the legislation are negligible.

Pharmacies

Figures from the National Pharmacy Association suggest that there are approximately 4,000 pharmacy companies in the UK. MHRA has assumed that medium and large scale companies (54 and 11 respectively) spend between 20 and 60 hours a year looking at the regulations[7]. From consultation responses and data from ASHE 2010, MHRA believes that salary costs range from £21 to £40 per hour. To this, MHRA has added 30% to account for non-salary costs. MHRA has also assumed that small and micro firms (826 and 3,083) do not refer to the legislation directly but instead rely on their industry bodies or on informal advice networks (this assumption was validated during consultation). Their costs of understanding regulations are therefore negligible. These assumptions yield annual costs ranging from £0.04 million to £0.22 million.

Pharmacy bodies

There are 5 main pharmacy trade bodies: the National Pharmacy Association; the Association of Independent Multiple Pharmacies; the Independent Pharmacy Federation, the Ulster Chemists' Association and Company Chemists' Association (CCA). Consultation responses suggest that each of the 5 main trade associations currently spends between 100 and 200 hours a year scrutinising the regulations. MHRA has assumed that the salary cost per hour is £20.77 (the average salary for pharmacists in 2010 according to ASHE statistics) and has added 30% to account for non-salary costs.

These assumptions yield annual costs of between £0.01 million and £0.03 million.

There are a number of other bodies in the UK and in devolved administrations that represent the interests of sectors of pharmacy and pharmacy technicians. MHRA approached 11 of these during informal consultation and those who replied told us that there would be negligible or unquantifiable impact on an annual basis of the new regulations.

There are also 4 negotiating bodies in each of the parts of the UK who told us that they seldom refer to medicines legislation. The costs of understanding the legislation are therefore assumed to be negligible.

[5] Estimates come from three sources within the pharmaceutical industry

[6] Taken from consultation responses. PAGB say average of £60 per hour, others are more conservative at approx £40, so £50 taken as an assumed average.

[7] Consultation responses from pharmacy companies suggest that this range is reasonable

Wholesalers

There are currently 1,744 pharmaceuticals wholesale dealer licences in the UK. MHRA assumes that this is an accurate estimate of the number of wholesale businesses. Of these 3 are national (and are assumed to be large sized), 11 are regional (assumed to be medium sized) and 1,730 are assumed to be micro and small sized businesses. Industry body membership is uncommon amongst small and micro wholesale businesses. The consequent lack of industry data makes it impossible to distinguish between medium, small and micro wholesale businesses. MHRA has received consultation responses from three wholesalers (one large and the others small or medium sized) that suggest that large and medium sized businesses each spend between 20 and 150 hours a year scrutinising the regulations, while small and micro businesses spend between 10 and 20 hours a year. Consultation responses also suggest that hourly staff costs (including non-salary costs) are £50.

These assumptions yield total annual costs of between £0.88 million and £1.84 million.

Private sector regulatory bodies

There are 19 professional groups (including doctors, pharmacists, nurses, herbalists and homeopaths) who can sell, supply or administer medicines.[8] The majority of these are regulated by 5 regulatory bodies: the General Pharmaceutical Council; General Medical Council; the Health Professional Council and the Nurses and Midwives Council, and the General Optical Council. MHRA has assumed that each of these 5 bodies spends between 1000 and 2000 hours a year scrutinising the current regulations.[9] The average hourly salary cost is assumed to be £19.47 (2010 ASHE average salary for accounting and legal services). 30% has been added to account for non-salary costs[10]. These assumptions yield total annual costs of between £0.13 million and £0.25 million.

Private Sector Professional Bodies

MHRA has assumed that each of the seven main bodies spends between 520 and 1040 hours a year scrutinising the current regulations. [11] The staff cost is assumed to be £25.31 (including 30% non-salary costs)[12]. These assumptions yield total annual costs of between £0.09 million and £0.18 million. The MHRA has found no evidence during consultation that any of the 12 other professional bodies representing professions routinely scrutinise legislation and so has treated their annual costs as negligible.

Current public sector costs of understanding the regulations

Pharmacy schools

There are 26 pharmacy schools in the UK. The Council of University Heads of Pharmacy Schools (CUHOPs) estimates that each school spends on average 10 days a year scrutinising the current regulations. The cost per day is £250.

These assumptions give annual costs of £0.07 million.

Primary Care Trusts and Strategic Health Authorities

Although the PCT and SHA structure of organising healthcare is in process of being dismantled in England, MHRA believes that the same regulatory functions will still need to be carried out in the NHS. Current PCT and SHA costs are therefore assumed to be representative of future costs.

[8] The full list of professionals includes physicians, nurses and midwives, dentists, opthalmologists, optometrists, herbalists, homeopathists, anthroposophic practitioners, chiropodists / podiatrists, occupational therapists, Orthoptists, Paramedics, Physiotherapists, prosthetists / orthotists, Radiographers, speech and language therapists, Osteopaths, Acupuncturists and naturopathists.

[9] Figures verified by the General Pharmaceutical Council and General Medical Council.

[10] Figures verified by the General Pharmaceutical Council and General Medical Council.

[11] Royal Pharmaceutical Society estimates.

[12] Verified by RPS and PSNI

There are ten SHAs in England. A consultation response from the NHS SHA Leads Group suggests that each SHA will on average spend 12.5 hours a year on understanding medicines regulations as they are currently drafted. MHRA assumes that the relevant hourly salary cost for SHAs is £20.77 (ASHE average hourly rate for pharmacists). With 30% added for non-salary costs the hourly rate is £27. These assumptions yield an annual cost of £3,375.

There are 151 PCTs in England. The NHS SHA Leads Group suggests that on average, each PCT will spend 27 hours a year understanding medicines regulations as they are currently drafted. In line with SHA costs, MHRA assumes an hourly staff cost of £27. These assumptions yield an annual estimated cost of £0.11 million

Current costs of legal advice

MHRA believes that routine legal advice is only sought by large pharmaceutical and other companies that bring new or highly modified regulated products to the market. Legal advice is assumed to be sought between 50[13] and 200[14] times per year. The cost of each consultation is between £300 and £500[15].

This yields annual costs of between £0.02 million and £0.1 million. None of this falls on micro or small businesses.

Total quantifiable current costs under the "do nothing" option

The total annual cost is estimated at between **£0.82 million** and **£5.42 million**.

Of this, MHRA estimates that

- micro businesses (excluding wholesale businesses) bear between £0.23 and £2.69 million
- small businesses (excluding wholesale businesses) bear between £0.07 million and £0.76 million
- small and micro wholesale businesses bear between £0.87 million and £1.73 million.

Unquantifiable current costs under the "do nothing" option

The MHRA regulated public and private sectors face considerable costs of litigation. Occasionally legal cases are argued because of different interpretations of the law. However these specific cases are too infrequent and variable to allow MHRA to estimate a credible annual average cost.

F. Costs and benefits of Option 1

The costs and benefits of Option 1 are described in detail in this section. A summary of the costs, and of the benefits that have been quantified, is set out in a table at the end of the section.

i) Costs:

MHRA and Department of Health (DH) costs

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.

Future MHRA and DH[16] costs of finishing the consolidation exercise are expected to be £0.25 million[17].

[13] Assuming 30 new active substances and 20 major changes to existing substances per year.

[14] Assuming that 100 large companies each seek advice twice a year.

[15] Estimate from Charles Russell LLP.

[16] DH lawyers will be required to work on areas of DH competence

[17] Based on the following assumptions: 1.5 FTE lawyers and 1 FTE policy official for 1.25 years. Lawyer costs £88,000 and policy official costs £65,000 per year (salary and non-salary costs)

Further annual costs of maintaining an informal consolidation of regulation on the website will be borne by MHRA. This will be necessary to ensure that the benefits of the initial formal consolidation exercise do not quickly dissipate as new legislation is introduced. The estimated cost is £2,000 a year[18].

Private sector transition costs

The costs estimated in this section relate to the costs of familiarisation with the new consolidated regulations and costs of changing guidance literature. NB: these are one-off costs.

Firms excluding wholesalers

From consultation responses from two pharmaceutical companies and one trade body, MHRA has assumed that all firms except micro and small pharmacy businesses spend between 15 and 45 hours familiarising themselves with the new consolidated regulations. As in section E, MHRA has assumed a total staff cost of £65 per hour. Micro and small pharmacy businesses are assumed to rely on their industry bodies and therefore do not need to familiarise themselves. This assumption was checked during consultation and found to be valid. The familiarisation costs are estimated at between £0.45 million and £1.36 million.

Wholesaler firms

From consultation responses from three wholesale firms, MHRA has assumed that micro and small wholesale firms will spend between 10 and 15 hours familiarising themselves with the new consolidated legislation. Medium and large firms are assumed to spend between 20 and 70 hours. These assumptions, combined with assumptions about staff costs in section E, yield estimated costs of between £0.88 million and £1.35 million.

Pharmacy representative bodies

From consultation responses from the RPS and PSNI, MHRA has assumed that each of the 5 main trade bodies spends between 100 and 200 hours on familiarisation, reflecting the need to be able to respond to members' questions efficiently. The remaining 11 bodies are expected to spend between 10 and 20 hours on familiarisation. These assumptions, combined with staff costs assumed in section E, yield estimated costs of between £0.02 million and £0.03 million.

Private sector regulatory bodies

From consultation responses received from the GPC and GMC, MHRA has assumed that each of the five bodies spends between 100 and 200 hours on familiarisation, reflecting the importance of a thorough knowledge of the layout of the new regulatory framework. This yields costs of between £0.01 million and £0.03 million.

Private sector professional bodies

From a consultation response received from the RPS, MHRA has assumed that the seven major professional bodies spend between 100 and 200 hours on familiarisation, reflecting the importance of a thorough knowledge of the layout of the new regulatory framework. The other twelve professional bodies are expected to spend a minimal 10 to 20 hours on familiarisation. These assumptions, combined with staff cost assumptions in Section E, yield costs of between £0.02 million and £0.04 million.

Total private sector familiarisation costs

Total costs to the private sector of familiarisation with the new regulations are estimated to lie between **£1.38 million** and **£2.79 million**.

[18] Based on 36 hours per year of a lawyer's time.

Of this total, between £1.15 million and £2.16 million is estimated to be borne by micro and small firms in the manufacturing and wholesale sectors.

Public sector familiarisation costs

Pharmacy schools

MHRA has assumed[19] that each of the 26 pharmacy schools spends between 20 and 30 days on familiarisation, in order to ensure students are properly informed about the law. The cost per day is assumed to be £250[20]. These assumptions yield costs of between £0.13 million and £0.20 million.

SHAs and PCTs

From consultation responses from several PCTs and SHAs, MHRA has assumed that both types of organisation will spend between 10 and 20 hours becoming familiar with the consolidated regulations. This assumption, combined with staff cost assumptions in Section E, yield total familiarisation costs of between £0.04 million and £0.08 million.

Total costs

The total one-off transition costs of Option 1 are estimated to lie between £1.75 million and £3.23 million. The annual costs, which fall entirely to MHRA, are £2,000.

ii) Benefits:

The quantified annual cost savings have been calculated by taking percentage decreases in the current baseline costs set out in Section E.

Quantified private sector cost savings in understanding the regulations

Manufacturers of pharmaceuticals, medicinal chemicals and botanical products (SIC 244)

From consultation responses from several manufacturers, MHRA has assumed that all businesses save between 10% and 50% of their current costs[21]. This yields annual cost savings of between £0.04 million and £2.25 million. Of this total, micro businesses benefit by between £0.23 million and £2.69 million, and small businesses by between £0.07 million and £0.76 million.

Pharmacies

From consultation responses from several companies, MHRA has assumed that medium and large pharmacy businesses will save between 5% and 15% of their current costs[22]. As noted in Section E, small and micro businesses are assumed to bear negligible costs of understanding regulations, and hence these businesses do not benefit from reduced costs. These assumptions yield annual cost savings of between £0.002 million and £0.033 million.

Pharmacy industry bodies

From consultation responses from the Company Chemists Association and Association of Multiple Pharmacies, MHRA has assumed that pharmacy bodies save between 5% and 15% of their current costs. This yields annual cost saving of between £0.001 million and £0.004 million.

[19] Estimates provided by CUHOPS

[20] Estimate provided by CUHOPS

[21] Consultation responses varied widely with at the low extreme, one manufacturer estimating a 10% saving, while at the other extreme, one major and one minor manufacturer each estimated a 50% saving. PAGB, representing the interests of "over the counter" medicine manufacturers, estimated a 20% to 50% saving.

[22] This is possibly a conservative estimate. One consultee suggested that the time might be halved.

Professional bodies

From a consultation response from the RPS, MHRA assumes that the professional bodies save between 10 and 20% of their current costs. This yields annual cost savings of between £0.01 million and £0.04 million.

Wholesalers

From consultation responses from three wholesalers, MHRA assumes that wholesalers save between 5% and 15% of their current costs. This yields cost annual savings of between £0.04 million and £0.28 million. Of this total, micro and small businesses are expected to benefit by between £0.04 and £0.28 million.

Private sector regulatory bodies

From a consultation response from the Royal Pharmaceutical Council, MHRA has assumed a saving of between 20% and 30% of its current costs. This yields annual cost savings of between £0.03 million and £0.08 million.

Total annual private sector cost savings in understanding regulations

Total annual private sector cost savings in understanding regulations are estimated to be between **£0.12 million** and **£2.67 million**.

Of this total, micro and small businesses are estimated to benefit by between £0.07 million and £1.99 million.

Quantified public sector costs savings in understanding the regulations

Pharmacy schools

MHRA has assumed that pharmacy schools save 50% of their current costs[23]. This yields annual cost savings of £0.03 million.

The NHS SHA Leads group has suggested that PCTs will save 80% of their current costs, while SHAs will save 67%. These assumptions yield total cost savings of £0.09 million.

Quantified private sector cost savings on legal advice

Bringing new active substances to market and major changes to existing substances

MHRA assumes that firms will save 50%[24] of their current legal advice costs. This yields annual cost savings of between £0.01 million and £0.05 million.

Unquantified value of reduction in legal risk

When regulatory obligations are unclear, the most common response among regulated businesses is to adopt a course of conduct that is certain to amount to compliance but goes beyond the minimum necessary. This is particularly common where businesses feel that their reputation would suffer significantly as a result of publicised enforcement action.

A clearer rulebook would allow regulated businesses to identify those areas where their current practice goes well beyond the minimum obligation, and to decide whether it is in their interests to continue.

MHRA has no information it can use to assess these cost savings, although they could be substantial.

[23] This is CUHOPS estimate

[24] Estimated by a private sector legal firm

Unquantified litigation cost savings

Clearer legislation should reduce the number of occasions on which readers of legislation disagree about its meaning. This should reduce the number of occasions on which disagreements result in litigation that produces costs for firms and for the public sector.

These cases are too infrequent and variable to estimate cost savings from clearer legislation.

Unquantified benefit: further opportunities

A unified and more easily comprehensible set of rules will act as a base for further initiatives designed to make the regulation of medicine more effective, transparent and proportionate. It will reduce the cost of carrying out such initiatives; in some cases the MHRA expects that it will allow initiatives to be identified that could not be identified under the current regime.

- For example, it should be much easier to produce improved guidance.
- It may be the case that inconsistencies of treatment or logical errors in the rules are easier to identify and remove.
- It should be easier to review whether a particular regulatory policy has worked as intended, without excessive unintended consequences, when the rules themselves are clearer.
- It would be much easier to carry out an Agency-wide review of criminal sanctions and civil penalties when those penalties can be located in a single document.

Thus, legislative consolidation is expected to improve the economy and efficiency of future projects. In practice, these future projects have yet to be defined sufficiently to allow quantification of the benefits. However, MHRA expects these benefits to be significant.

iii) Option 1 summary of quantified costs and benefits

To summarise:

- MHRA has monetised all the costs of Option 1
- MHRA has monetised only certain of the benefits of Option 1. It has not attempted to monetise the impact of reduce legal uncertainty or the further opportunities created by consolidation.

The NPV estimates provided below are therefore highly conservative. The MHRA believes that they are likely to understate significantly the economic benefits of Option 1.

Incremental costs, benefits and net benefits are summarised in the table below:

		Costs (£'000s)			Benefits (£'000s)			Net (£'000s)		
		Transition	Annual	10 year PV	Transition	Annual	10 year PV	Transition	Annual	10 year PV
Private sector	Low	1342	0	1297	0	123	938	-1342	123	-1694
	High	2724	0	2632	0	2650	20163	-2724	2650	18866
Of which businesses	*Low*	*1294*	*0*	*1250*		*89*	*678*	*-1294*	89	-1860
	High	*2627*	*0*	*2538*		*2537*	*19299*	*-2627*	2537	18049
Of which micro/small	*Low*	*1120*	*0*	*1082*	*0*	*71*	*538*	*-1120*	*71*	-1490
	High	*2099*	*0*	*2028*	*0*	*1985*	*15103*	*-2099*	*1985*	14021
Public sector	Low	408	2	414	0	119	908	-408	117	392
	High	513	2	516	0	119	908	-513	117	494
Total	Low	1750	2	1710	0	243	1846	-1750	241	-1301
	High	3238	2	3147	0	2770	21071	-3238	2768	19360

The net present value of the costs and the quantified benefits over the ten year appraisal period is estimated to lie between -**£1.3 million** and **£19.4 million**.

iv) Risks and uncertainty

The MHRA is not aware of any significant, unmitigated risks associated with this intervention.

v) One in, one out

Equivalent annual costs have been calculated using mid-point estimates of the ranges given in the table above. The equivalent annual costs to businesses are £0.220 million, and the equivalent annual benefits are £1.160 million, giving **a net equivalent annual impact of £0.940 million**. MHRA believes that the consolidation exercise qualifies as an "out".

G. Specific impact tests

Economic

Competition assessment

UK markets for originator medicines that contain innovative active substances are nation-wide, 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 medicines are nation-wide and experiences some static competition based on price.

Markets for medicines wholesaling services vary by scope, scale and geography. MHRA believes that there are three national wholesalers who supply a very broad range of medicines (they are full-line wholesalers). These three compete with a further 11 wholesalers who operate regionally and are also full-line. There is also a large number of much smaller wholesalers who generally stock a smaller range of medicines (short-line wholesalers). Competition is strong among all wholesalers. (Information comes from "A Critique of Direct to Pharmacy Distribution, Donald MacArthur, 2010)

Markets for pharmacy services experience competition that is geographically local and mostly static, based on the quality of service. There is some evidence of innovative services such as patient reminders for repeat prescriptions.

It is plausible to argue that the consolidated regulations would remove a barrier to entry – the sunk costs of attaining knowledge of the complicated legal landscape. However, MHRA believes that these barriers are either too small to be of significance (wholesale markets) or are not the most binding constraint to entry. More important barriers include the sunk costs of R&D in originator medicines markets and the maintenance of professional standards among pharmacists.

The consolidation exercise will make no changes to the substance of medicines legislation and hence MHRA believes that there will be no material impact on competition.

Small firms impact test

In assessing the impact on small firms, MHRA contacted relevant industry bodies. With the exception of wholesalers, all micro and small businesses in the regulated sectors are well represented by industry bodies.

The only costs that small firms will bear as a result of the consolidation project are the one-off costs of familiarisation with the simplified regulations. MHRA believes that micro and small pharmacies (3909 firms) will not bear any familiarisation costs because they will continue to rely on their trade associations for legal advice. This assumption has been verified by responses from small businesses and their representative bodies during the consultation.

Of the remaining small and micro firms, wholesalers (1730 firms) are expected to bear familiarisation costs of between £500 and £750 each, while pharmaceutical and botanical medicines manufacturers (295 firms) are expected to bear costs of between £975 and £2925 each.

The total, one-off transition cost for small and micro firms is estimated to be between £1.15 million and £2.16 million.

These costs will be set against benefits with a net present of between £0.54 million and £15.1 million (over a ten year period and using a 3.5% discount rate).

The estimated impacts on small firms and on micro-businesses are presented in more detail in Sections E and F of this Impact Assessment.

MHRA therefore believes that the burdens on micro and small businesses will be small and that **the net benefit for micro and small business will be substantial. Taking the mid-point estimates of cost and benefits, MHRA estimates that the NPV for small and micro businesses will be £6.3 million.**

The consolidation exercise is out of scope of the **microbusiness moratorium** because it qualifies as an "out". Micro firms will receive a net benefit from legislative consolidation.

Equality

We do not consider that the problem of fragmented legislation falls more heavily on the groups with 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. The problem in comprehension of medicines legislation is universal and applies to anyone who uses the legislation, both specialists and lay readers.

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

Health and well being

We have considered the health impact screening questions and do not consider that consolidated medicines 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

Medicines legislation contains criminal offences and these have been rewritten and grouped together in the consolidated text to reduce the number of offence provisions. This will not change how the offences are used and have no impact on the justice system, so a full Justice Impact test is not needed. We have liaised with Ministry of Justice in reaching this conclusion.

Rural Proofing

Our options have no significant impact on rural communities. The consolidation is not about the delivery of services.

Sustainable development

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

Annex A – description of the consolidated regulations

Part	Description
Part 1 – General	Contains important provisions that apply to much of the rest of the consolidation. These include a description of the role of Ministers and general definitions, including “medicinal product” and “advertisement”. There are further definitions in other parts of the consolidated regulations, for terms that are only used in those particular parts.
Part 2 – Administration	Allows for the continuing functioning of a number of advisory bodies, including the Commission on Human Medicines and the British Pharmacopoeia Commission. It also provides rules for the appointment and role of expert advisory groups.
Part 3 – Manufacturing and wholesale dealing	With several associated schedules, this Part sets out the rules for manufacturing, importing and wholesale dealing. It requires that these activities be the subject of a licence and establishes what the licensing authority must consider when assessing an application for a licence. It also provides rules around the suspension, revocation, and varying of licences and sets out requirements for Responsible Persons and Qualified Persons. This Part implements Titles 4 and 7 of Directive 2001/83/EC and includes provisions that were previously in Part 2 of the Medicines Act 1968 and the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789).
Part 4 – Requirement for authorisation	The requirement that medicinal products be the subject of whichever is appropriate of a marketing authorisation, homeopathic certificate of registration, traditional herbal registration or Article 126a authorisation is a central feature of the legal framework and set out in its own Part, along with provision for its enforcement.
Part 5 – UK marketing authorisations	Contains detailed requirements regarding marketing authorisations. It sets out the material that needs to accompany applications for authorisations, and makes specific provision for generic medicinal products, biological medicinal products, products with well-established medicinal use, and new combinations of active substances. It also establishes the criteria that are considered in determining whether a product needs to be subject to prescription requirements. The Part imposes certain obligations on authorisation-holders, such as a requirement to take into account scientific and technical progress, and contains rules relating to revocation, variation, suspension, withdrawal of authorisations. Finally, it contains enforcement provision for medicinal products that are subject to the Paediatric Regulation. This Part implements Title 3, Chapter 1 of Directive 2001/83/EC and consolidates material found for the most part in the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (SI 1994/3144)
Part 6 – Certification of homeopathic medicinal products	Implements Chapter 2, Title 3 of Directive 2001/83/EC and consolidates the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994/105). It describes the homeopathic medicinal products to which it applies and sets out information that must be supplied with an application for a certificate of registration. As with marketing authorisations, it imposes certain obligations on registration holders and sets out rules regarding revocation, variation, withdrawals, and suspensions.
Part 7 – Traditional herbal registrations	Describes the traditional herbal medicinal products that are subject to the Part and sets out the information that must accompany an application for a traditional herbal registration. It imposes certain obligations on registration-holders and sets out rules regarding revocation, variation, withdrawals, and suspensions. This Part implements Chapter 2a, Title 3 of Directive 2001/83/EC and consolidates material currently found in the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (SI 2005/2750).
Part 8 – 126a authorisations	A short part that implements Article 126a of Directive 2001/83/EC. This article permits Member States, for justified public health reasons, to authorise the placing on the market of medicinal products authorised in another EEA state in

	the absence of a UK marketing authorisation.
Part 9 – Borderline products	Establishes a process that may be followed when the licensing authority determines provisionally that an unlicensed product is a medicinal product and therefore subject to regulation as such. It permits persons supplying the product to make written and oral representations to the contrary, and for final determination. These provisions are currently found in the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (SI 1994/3144).
Part 10 – Exception to requirement for marketing authorisation	Brings together exceptions from certain licensing requirements that are found in several different statutory instruments. These include the provision for "specials" in Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (SI 1994/3144) in accordance with the derogation found in Article 5(1) of Directive 2001/83/EC, These are unlicensed medicinal products that can be supplied providing that certain conditions are met. The part also makes provision for parallel import licences, exempt advance therapy medicinal products and the supply of unlicensed medicines in response to the spread of toxic substances or nuclear radiation.
Part 11 – Pharmacovigilance	Part 11 implements Directive 2010/84/EU, which amends Directive 2001/83/EC in order to introduce a strengthened, clarified and more proportionate regime for pharmacovigilance in the EU market. [NB: implementation of Directive 2010/84/EU is subject to a separate impact assessment.]
Part 12 – Dealings with medicinal products	Brings together many provisions currently found in Part III of the Medicines Act 1968, The Medicines (Pharmacy and General Sale – Exemption) Order 1980 (SI 1980/1924), and the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830), among others. Together, these provisions establish rules relating to the sale supply and administration of medicinal products related to their classification as general sale list, pharmacy, and prescription only. It also creates a number of exemptions from the basic rules for hospitals, certain professionals and supply under patient group directions (PGDs).
Part 13 – Packaging and leaflets	Implements obligations found in Title 5 of Directive 2001/83/EC by consolidating provisions currently found in Part 5 of the Medicines Act 1968, the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (SI 1994/3144), and The Medicines (Child Safety) Regulations 2003 (SI 2003/2317). It sets out the information that must appear on packaging and in leaflets, and contains specific rules for Braille, radionuclides, and homeopathic and herbal medicinal products. In the consolidated regulations we have reflected the current legal provisions in relation to labelling requirements.
Part 14 – Advertising	Implements Title 8 of Directive 2001/83/EC and consolidates the Medicines (Advertising) Regulations 1994 (SI 1994/1932) and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933). It contains a variety of prohibitions on advertising including those relating to unlicensed medicines, prescription medicines, recommendations by scientists, and advertisements aimed at children. In addition, it sets out the information that needs to be included in advertisements and establishes rules for sampling, the promotion of medicinal products by medical sale representatives, and hospitality at meetings. This Part also contains a chapter called 'Monitoring of Advertising', which creates a process by which Ministers can determine whether an advertisement breaches these requirements, and in certain circumstances require that corrective action is taken. Finally, it requires Ministers to consider complaints about advertisements and permits Ministers to apply to a court for an injunction prohibiting a particular advertisement.
Part 15 – British Pharmacopoeia	A short part that provides for the publication of the British Pharmacopoeia and related documents. It consolidates several provisions currently found in Part 7 of the Medicines Act 1968.
Part 16 – Enforcement	Sets out how the consolidated regulations are to be enforced in England, Wales, Scotland, and Northern Ireland. It also provides inspectors with powers to enter, inspect, and search premises and seize medicinal products. Where the premises in question are private dwellings, it requires that 24 hours' notice be given to the occupier.

Part 17 – Miscellaneous and general	Contains a variety of technical provisions, including those relating to prosecutions, defences, decisions made under the regulations, and liability. It also introduces Schedules that contain transitional provisions, consequential amendments, and repeals and revocations.

Annex B – principal statutory instruments being revoked through consolidation and not consolidated in effect

The following statutory instruments are redundant and so are, at least in part, being revoked and not consolidated in effect. Much of them have been subject to policy (as opposed to merely consequential) amendments by subsequent statutory instruments, and these will also be revoked.

Legislation title	Year	No.	Why redundant
Medicines (Standard Provisions for Licences and Certificates) Regulations 1971	1971	972	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971	1971	973	Redundant because superseded by subsequent medicines legislation.
Medicines (Control of Substances for Manufacture) Order 1971	1971	1200	Relates to products now regulated by veterinary medicines legislation.
Medicines (Surgical Materials) Order 1971	1971	1267	Relates to products now regulated as medical devices under the Medical Devices Regulations 2002 (SI 2002 618), as amended.
Medicines (Importation of Medicinal Products for Re-exportation) Order 1971	1971	1326	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971	1971	1410	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971	1971	1450	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972	1972	1200	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration

			under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Data Sheet) Regulations 1972	1972	2076	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Extension to Antimicrobial Substances) Order 1973	1973	367	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Renewal Applications for Licences and Certificates) Regulations 1974	1974	832	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Exemption from Licences) (Ingredients) Order 1974	1974	1150	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Dental Filling Substances) Order 1975	1975	533	Relates to products now regulated as medical devices under the Medical Devices Regulations 2002 (SI 2002 618), as amended.
Medicines (Exemption from Licences) (Wholesale Dealing in Confectionery) Order 1975	1975	762	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Specified Articles and Substances) Order 1976	1976	968	Relates to products now regulated as medical devices under the Medical Devices Regulations 2002 (SI 2002 618), as amended.
Medicines (Breathing Gases) Order 1977	1977	1488	Provides that gases sold for non-medicinal reasons are not medicinal products for the purposes of regulation. This is not necessary, as the products can be classified as non-medicinal under the definition of medicinal product in the consolidated regulations.

Medicines (Fluted Bottles) Regulations 1978	1978	40	Fluted bottles are no longer manufactured and pharmacists and manufacturers (where this was a provision of the marketing authorisation) can therefore no longer comply.
Medicines (Exemption from Licences) (Assembly) Order 1979	1979	1114	Provides an exemption from requirements under section 8(2) of the Medicines Act 1968 from requirements for a manufacturer's licence. We do not see that this instrument creates any necessary or useful safeguards on top of those in other medicines legislation.
Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979	1979	1585	Relates to products now regulated as medical devices under the Medical Devices Regulations 2002 (SI 2002 618), as amended.
Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979	1979	1759	Relates to products now regulated as medical devices under the Medical Devices Regulations 2002 (SI 2002 618), as amended.
Medicines (Cyanogenetic Substances) Order 1984	1984	187	Extends the scope of the Medicines Act 1968 to include cyanogenetic substance. This is not necessary, as cyanogenetic substance meet the definition of medicinal product in the consolidated regulations.
Medicines (Exemption from Licences) (Importation) Order 1984	1984	673	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC (see paragraphs 6.3 to 6.5 in the consultation document).
Medicines (Control of Substances for Manufacture) Order 1985	1985	1403	Relates to products now regulated by veterinary medicines legislation.
Medicines Act 1968 (Hearings by Persons Appointed)(Scotland) Rules 1986	1986	1700	Redundant because superseded by subsequent medicines legislation.
Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986	1986	1761	Redundant because superseded by subsequent medicines legislation.
Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) 1992	1992	605	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration under Directive 2001/83/EC.
Medicines (Exemption from Licensing) (Radiopharmaceuticals) Order 1992	1992	2844	Redundant because superseded by subsequent medicines legislation.
Medicines (Applications for Grant of Product Licences—Products for Human Use) Regulations 1993	1993	2538	Redundant because it relates to the product licensing regime under the Medicines Act 1968 that is being incorporated by the consolidated regulations into the unified scheme for authorisation and registration

			under Directive 2001/83/EC
Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995	1995	309	The intention is that, once the consolidated regulations come into force, the Advisory Board on the Registration of Homeopathic Products will not be provided for in law.
Herbal Medicines Advisory Committee Order 2005	2005	2791	The intention is that, once the consolidated medicines regulations come into force, the Herbal Medicines Advisory Committee will no longer be provided for in law.