EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (AMENDMENT) REGULATIONS 2007

SI 2007 No. 604

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, and is laid before Parliament by Command of Her Majesty.

   This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This SI amends relevant regulations which set out the fees payable by hospital blood banks and blood establishments in relation to services the Medicines and Healthcare products Regulatory Agency (MHRA) undertakes as the Competent Authority acting on behalf of the Secretary of State for Health for regulating blood banks and establishments. It increases the fees payable by amounts ranging from 10% to 50%. The overall effect of the increases is to increase fees by 40%. The fees are targeted to ensure that actual costs for specific services are met through the fees charged in line with Treasury guidance on fees and charges.

3. Matters of special interest to the JCSI

3.1 Under the Regulations, the Secretary of State for Health is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance and is the Competent Authority for the purposes of the EC directives relating to the safety and quality of blood. The Secretary of State's functions are performed by the MHRA.

3.2 The MHRA is financed by means of a Government trading fund and does not receive any central funding for this area of its work. Therefore, any work it does in relation to the performance of functions under the Regulations must be funded by fees charged for the work. The MHRA is also the UK medicines and devices regulator and is fully funded for its medicines regulatory work through fees charged to the pharmaceutical industry. The devices part of the work is mostly funded by central funds (via the Department of Health) because it does not have the ability to charge fees for all of its work. However, it does raise some funding directly through fees charged for specific services.

3.3 The fee increase for this particular area is above the rate of inflation for several reasons. These fees were introduced in October 2005 and reflected the scale of fees, at that time, for similar work (particularly inspection work) that the MHRA undertook for other sectors. The MHRA undertook a rigorous costing exercise during 2005/2006 which identified that some areas of its work were not recovering total costs. In particular, the exercise identified that inspection fees were under-recovering actual costs by a significant amount. Following a consultation exercise, all other MHRA fees were increased on 1st April 2006 by 17% overall, with inspection fees being increased by 42.7%. Because the fees relating to blood banks and blood establishments had only been introduced in October 2005, a decision was made not to increase them in line with

other MHRA fees six months later, but to wait until the following review of costs and fees for 2007/2008.

3.4 The costing review undertaken by MHRA for 2007/2008 shows that the inspection area is still under recovering and proposals to increase inspection fees by a further 5.5% have been made and are being implemented. In order to bring these fees in line, and ensure full recovery of costs, they need to be increased by around 50%. Other related fees have not been increased for over 18 months and a costing exercise also showed that these need to be brought into line with actual costs. This will ensure that the MHRA is fully funded for its functions in relation to public health protection.

3.5 The fee increases in this instrument are made in order to ensure that the fees charged for each area of activity properly reflect the cost of that activity in line with Treasury guidance on fees and charges. There is no opportunity to fund this work from elsewhere (including central funds), no subsidies are available and it is not possible to cross-subsidise from other income.

4. Legislative background

4.1 This instrument amends regulation 22 of the Blood Safety and Quality Regulations 2005, in order to increase the fees payable by blood establishments and hospital blood banks, for the reasons given elsewhere in this memorandum. The instrument also corrects cross-references which are no longer correct following the amendment of the Regulations by the Blood Safety and Quality (Amendment) Regulations 2006 (SI 2006/2013)..

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The MHRA is an Executive Agency of the Department of Health. Under the Blood and Quality Regulations 2005 the Secretary of State for Health is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance compliance assessments. The Secretary of State's functions are performed by the MHRA. This instrument only affects this element of the Agency's work.

7.2 The MHRA is financed by means of a Government trading fund. By virtue of the Government Trading Funds Act 1973, the MHRA has an obligation to at least break even taking one year with another and to set fee levels to achieve this.

7.3 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. It has taken measures to deliver efficiencies and continues to do so. This instrument amends the

level of fees charged by MHRA in order to ensure that the full cost of the work undertaken is recovered.

7.4 The cost of compliance associated with this instrument is estimated to be in the region of an additional £215k. In addition, the Agency is also proposing efficiency gains from within its current running costs. There are no associated recurring or non-recurring costs for those affected.

7.5 All hospital blood banks and blood establishments are affected – many of these are NHS bodies. All of these organisations have been consulted on the proposals to increase these fees. The formal consultation period lasted for 11 weeks, but relevant organisations were alerted before then that substantial increases would be proposed. We issued consultation notices to all relevant bodies and received 3 replies only. These expressed concern at the level of increase and that it would have to be met from existing budgets. MHRA considered the responses, but it is unable to reduce the costs for this sector as it has no mechanism for recovering the shortfall and it is unable to cross-subsidise by increasing fees elsewhere. For hospital blood banks, the only additional costs that they will all have to bear are the fees linked to the two reporting systems (reporting adverse events related to blood, and providing a report detailing compliance with blood safety requirements). Inspections are not carried out every year but in accordance with assessed risk. A full RIA has been prepared and is attached to the memorandum. Copies can also be obtained from Karen Salawu, Fees Policy Unit, Room 16-159 Market Towers, Tel: 020 7084 2216, e-mail: karen.salawu@mhra.gsi.gov.uk.

7.6 The MHRA has no current proposals to consolidate any of the regulations amended by this instrument, although it continues to keep the matter under review

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 The impact on the public sector is that costs for blood banks and blood establishments will increase by around 40% in 2007/2008 and the costs will have to be met by current budgets. The MHRA has considered the impact on these bodies but is unable to cross-subsidise the cost of this work from elsewhere. However, it is taking a risk-based approach to its responsibilities in this area which will mean that only necessary costs will be incurred and those establishments that are fully compliant will receive fewer inspections and therefore can expect to pay less. It is important that the work is properly resourced if it is to achieve the public health protection for which the inspection system was introduced.

9. Contact

9.1 Sue Jones at MHRA Tel: 020 7084 2652 or e-mail: sue.jones@mhra.gsi.gov.uk can answer any queries regarding this instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE

THE BLOOD SAFETY AND QUALITY (AMENDMENTS) REGULATIONS 2007

2. The Purpose and Intended Effect of the Measure

Background

2.1 These Regulations further amend the Blood Safety and Quality Regulations 2005 to enable the Medicines and Healthcare products Regulatory Agency (MHRA) to increase the fees it currently charges for regulatory activities it carries out on behalf of the Secretary of State.

2.2 The proposed amendments fulfil the obligation that the MHRA, a Government Trading Fund established under the Government Trading Fund Act 1973, is required to recover the full costs of the services it provides and cross subsidy is not permitted. Under the Blood Safety and Quality Regulations 2005 the Secretary of State for Health is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. This functions are carried out by the MHRA acting as the Competent Authority on behalf of the Secretary of State. The fees charged by the MHRA for these services are monitored and reviewed annually to ensure, as far as possible, that the fees charged reflect the cost of the work undertaken. This is in line with Treasury guidance on Fees and Charges.

Objectives

2.3 These Regulations amend existing legislation in connection with the regulation of blood banks and other blood establishments. The proposal for 2007/2008 is to achieve full cost recovery of the work undertaken by the MHRA as the Competent Authority.

2.4 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.

Rationale for Government intervention

2.5 The quality and safety of blood and blood products in the UK is already amongst the best in the world but their use, like most medicinal procedures, can never be free of risk. The implementation of SI 2005 (No 50) and subsequent amendments further improved the safety and quality of the blood supply.

2.6 Ultimately, if the MHRA were to be insufficiently resourced to carry out its responsibilities, the Agency could be unable to fulfil its obligations in relation to its role as Competent Authority and the protection of public health. The Agency, as a Trading Fund (TF),

would be unable to sustain its financial position. Staff numbers would have to be cut to be able to break even taking one year with another as required by the TF Order. If the MHRA is not adequately resourced for the work it undertakes there could be a risk to human health in the long term through inadequate regulation and inspection of blood banks and blood establishments. This could occur, for example through bad clinical practices not being spotted and remedied and thus contaminated blood products being released for patient use.

2.7 It is therefore important that the MHRA is able to gain sufficient income from fees to resource its functions effectively. However, it is also recognised that the Agency must carry out its responsibilities efficiently and in accordance with the Government's principles on Better Regulation, so that regulation is proportionate, targeted and risk-based. Hospital blood bank inspections are targeted according to assessed risk and will generally take place every few years.

2.9 The MHRA's main areas of work are the regulation of medicines and medical devices. It covers the cost of all the work carried out in relation to medicines regulation (and a small proportion of the work relating to devices regulation) through fees charged. It has an established fees system which regularly monitored and costed to ensure that fees charged for specific services are targeted accordingly.

2.8 The rationale behind these fee proposals is therefore to ensure a fee regime that enables the Agency to recover its costs, fulfil its role in safeguarding public health; and also uses the resources from fee income to target improvement in this area of the Agency's business.

3. Consultation

3.1 These proposals were consulted with HM Treasury, and of Department of Health colleagues. A formal 11 week consultation took place between November 2006 and February 2007 on these and other MHRA fees. Only three responses were specifically about these fees and expressed concern on the impact the increases would have on the NHS.

4. Options

4.1 Three options for the main proposals have been identified:

Option 1 - increase fees as proposed to cover costs.

Option 2 - make no changes.

Option 3 - increase fees by an inflationary figure across-the-board.

4.2 Option 1 will ensure that the correct fee is charged to cover the cost of each area of work undertaken and ensure that MHRA's obligation as a Trading Fund to recover full costs of the service it provides without cross subsidy.

4.3 Option 2 would freeze costs at 2005/2006 levels (as there were no increases in 2006/2007 because it was felt it was too early to increase the costs so soon after the MHRA had taken on this work). Option 2 would mean that the Agency would not be fully recovering the cost of this work.

4.4 Option 3 would increase fees by, say, 3.5% across the board. However, this would mean that fees were not targeted, nor would they recover full costs of the work undertaken.

5. Costs and Benefits

Sectors and groups affected

5.1 The NHS and other organisations that store or manufacture blood products would be affected.

5.2

- An NHS hospital blood bank requiring to pay annual haemovigilance fee, an annual compliance fee and has a short inspection in year would have paid £1,534 in 2006/2007 but for the same services in 2007/2008 would pay £2,158 – a difference of £624. Hospital blood bank inspections are targeted according to assessed risk and will generally take place every few years. The same hospital blood bank, if there were no inspection in year, would pay £1,032 in 2007/08 instead of £775 in 2006/7 – an increase of £257.

- A new establishment applying for an application for authorisation would have been charged £2,444 in 2006/2007, but would pay £2,688 in 2007/2008 – an increase of £244.

- An existing large sized blood establishment paying an annual haemovigilance fee and receiving an inspection in year would pay £9,104 in 2006/2007 but this would increase to £13,585, an increase of £4,481 in 2007/2008.

Benefits

5.3 The key benefit is the protection of public health in ensuring the safety and quality of the supply of blood in the UK. In addition stakeholders will continue to see benefit from improvements in service levels from the MHRA.

Costs

5.4 Costs to individual organisations and bodies will increase by around 10% for some activities (e.g. authorisation applications and changes to authorisations) but by around 50% for costs in relation to inspections.

5.5 The MHRA undertook a rigorous costing exercise in 2005/2006 and identified that it was significantly under-recovering costs in relation to inspections in particular. It increased its general inspection fees by 42.7% in April 2006 (other individual fees charged by the MHRA were increased between 10% and 19% following the costing exercise) . The fees set in these regulations originally (in October 2005) were set at the same level as for inspections for medicines applications at that time. This is because the activity, and thus the cost of the work, is broadly the same for an inspection of a pharmaceutical industry as they are for blood establishments (i.e. these inspections are of the same type, require the same amount of time (depending on size) and the same grade of staff).

5.6 The new fees for blood banks and establishments were introduced in October 2005. The MHRA increased its other inspection fees (following consultation) in April 2006. As the blood regulation fees had only been in place for less than 6 months, it was decided not to increase these fees at the same time (i.e. April 2006) despite indications showing that costs for these inspections would have been the same as for other inspections. However, the MHRA reviews it fees on an annual basis and makes proposals for changes to take place in April each year. It has already consulted on increasing general inspection fees again in April 2007, by a further 5% to match the costs of the work undertaken. The fees for inspections of blood banks and blood

establishments need to be aligned now to avoid continuing under-recovery of costs but this results in a significant increase of around 50% for each inspection undertaken.

5.7 There are no associated policy costs or administration costs from these proposals. These regulations implement an increase in fees that already exist. There are therefore no associated additional administration costs for companies as there are no new fees or new procedures being implemented.

Impact on Small Business

6.1 These regulations will impact on all organisations within this sector equally. There will not be any specific increase affecting only small businesses. There are no "small businesses", as such, involved in this area of work but NHS and other public health organisations will be affected by these regulations. The increase in income for the MHRA from the whole of this sector in 2007/2008, using estimated projections of numbers of inspections (20 for blood establishments and 50 for hospital blood banks) and number of compliance reports, etc. is around £215k over the amount charged through fees in 2006/07. There are fewer inspections of hospital blood banks (50 compared to 66) planned for 2007/2008 reflecting the Agency's move to risk-based inspections. The average increase in costs for individual bodies in this sector comparing 2006/07 estimated volumes with 2007/08 totals around £500 - £600 each although increased costs for individual organisations and bodies will be greater if they have an inspection in year as inspection fees are increasing by a much higher amount. The overall increase in costs to this sector is around 40%.

7. Competition Assessment

7.1 The market for the supply of human blood and blood products – including its collection, testing and processing, storage and distribution of human blood and blood components has been studied by the National Audit Office (NAO). It is not believed that these proposals will increase any existing barriers to entry and harmonisation. The Regulations introduce no change in existing UK practice.

8. Equality Impact Assessment:

8.1 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.

9. Enforcement, Sanctions, and Monitoring

9.1 These Regulations will be enforced by the Competent Authority through a system of licensing, inspection and compliance verification. Breaching these provisions would constitute an offence. The Finance Division of the Agency is responsible for raising invoices and collecting revenue for the Agency. There are certain sanctions where some fees are paid late. The MHRA monitors and assesses costs against fees on an annual basis and proposals for change are made through a consultative process and are subject to parliamentary approval. The MHRA is working to improve its efficiency and the introduction of more risk-based inspections ensures that compliant bodies are not inspected unnecessarily. More compliant bodies will have lower costs.

10. Implementation and delivery plan

10.1 The new fees will apply to relevant MHRA services undertaken on or after the 1st April 2007. The new fees will be advertised on the MHRA's website and all those affected have been made aware through the consultation exercise that changes are imminent.

11. Post-implementation review

11.1 The new fees and the anticipated income through estimated volumes have been matched with the Agency's budget plan for 2007/2008.

11.2 MHRA fee levels are subject to continuous rigorous monitoring and review with a view to making annual amendments (where necessary) to ensure that, as far as possible, the cost of the work undertaken by the MHRA is reflected in the fees charged to industry, NHS and other establishments. In addition, the Agency is seeking efficiencies from within its working practices to provide a better standard of service from within current resources. Where this results in a reduction or freezing of costs, this will be reflected in any future proposals for changes to associated fees.

12. Summary and Recommendations

12.1 Option 1 best achieves the objective of ensuring that costs reflect the actual cost of the work undertaken by the MHRA. It will allow the MHRA to undertake its responsibilities for protecting public health. It will help to target resources.

Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social, policy and administrative
1	- protection of public health by quality of blood supply and ensuring swift action is taken in response to serious adverse events and reactions, - MHRA fully funded to enable it to fulfil current functions and new requirements without loss of quality	- increase in current inspection fees of 50% (inspections undertaken every 2-3 years) - increase in other costs annually by 10% Total cost of compliance in 2007/08 across all organisations in this sector approx £695k compared to £480k in 2006/2007. The increase in costs taking 06/07 with 07/08 is a total of £215k (around 40% overall) There are no associated administrative or policy costs as these regulations implement an increase in already existing fees.
2	No additional cost to establishments from MHRA fees	- potential for serious public health risk due to inadequate funding of service – inspections and other monitoring activities would be too infrequent ; - delays for establishments in having inspections and monitoring of this work; - MHRA inadequately funded and

		not able to fulfil public health responsibilities; - failure to meet terms of Trading Fund Order; - Total annual cost would be around £480k
3	Some resources for Agency to meet additional regulatory requirements, though not sufficient to maintain current levels of service	- Possibility of cross-subsidisation of fees contrary to Treasury guidelines or need to seek central Government funding to cover losses – total cost would be around £497k; - Inability of Agency to recruit essential staff, hampering ability to undertake this work; - potential for serious public health risks if unable to cover the work

13. Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that benefits justify the costs.

Signed by the responsible Minister ...Caroline Flint.....

Date ..28th February 2007.....

14. Contact point

Any enquiries about these Regulations should be made, in writing to:

Mrs Karen Salawu
Fees Policy
Medicines and Healthcare products Regulatory Agency
16-160
Market Towers
1 Nine Elms Lane
London SW8 5NQ Tel: 020 7084 2216 e-mail:karen.salawu@mhra.gsi.gov.uk