EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE AND MEDICAL DEVICES (FEES AMENDMENTS) REGULATIONS 2007

2007 No. 610

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 instrument amends the regulations which set out fees payable by the pharmaceutical industry and the medical devices industry in relation to services provided by, and regulatory functions carried out by, the MHRA in relation to medicines for human use and medical devices on the UK market. It increases the fees payable ; the overall effect of is to increase fees by 4.9% for medicines and 20% for medical devices, although some fees have not been increased. The instrument also makes various changes to the rules setting out when certain fees are payable and introduces 4 new fees.

3. Matters of special interest to the JCSI

3.1 Following the signing of this instrument, the Department has identified that the instrument had not been validly made, in so far its provisions purport to be made under section 1(1) and (2) of the Medicines Act 1971, for the reasons set out in the following paragraph. As this instrument is partially invalid, the Department proposes to make a second instrument to revoke and replace it as soon as practicable. The second instrument will contain a provision revoking this instrument and will be made jointly with the Department for Agriculture and Rural Development for Northern Ireland, but will otherwise contain provisions identical to this instrument. In accordance with paragraphs 3.4.11 to 14 of Statutory Instrument Practice, the second instrument will be made available free of charge to all known recipients of this instrument.

3.2 Section 1(1) and (2) of the 1971 Act provides for "the Ministers" to make regulations prescribing various fees. Section 1(3) of the 1971 Act provides that expressions used in the Act have the same meaning as in the Medicines Act 1968 as amended by the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); section 1(1) of the 1968 Act as so amended provides that "the Ministers" means the Secretaries of State respectively concerned with health in England, in Wales and in Scotland, the Minister of Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland. By virtue of section 1(3) of the 1971 Act, article 2(1) of the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142), article 3(1)(c) and (7) of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794) and the Northern Ireland Acts 1998 and 2000, the powers conferred by section 1(1) and (2) of the 1971 Act may now be exercised by the Secretary of State, the Department of Health, Social Services and Public Safety in Northern Ireland and the Department of Agriculture and Rural Development in Northern Ireland, acting jointly. In error, this instrument was signed only by the Secretary of State and the Department of Health, Social Services and Public Safety. The Department had mistakenly been of the view that the definition of "the Ministers" in section 1(1) of the 1968 Act as amended by the Veterinary Regulations 2006 (S.I. 2006/2407) applied to the 1971 Act, by virtue of section 1(3), in which case the agreement and signature of the Department for

Agriculture and Rural Development would have been unnecessary. That interpretation was not correct; in particular, section 20(2) of the Interpretation Act 1978 does not apply to the reference in section 1(3). The reference to "the Ministers" in section 1 of the 1971 Act is therefore a reference to "the Ministers" as defined by section 1(1) of the 1968 Act as it stood in 1971, subject only to the transfers of functions effected by SI 1999/3142 and 2002/794.

3.3 In so far as the instrument did not purport to be made under the Medicines Act 1971, it was properly made by the Secretary of State, acting alone, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and, with the consent of the Treasury, section 56(1) and (2) of the Finance Act 1973. The Department's view is that in so far as the provisions of this instrument are made under those sections, it is valid. In the light of this partial validity, the Department did not consider it appropriate to withhold laying the defective instrument and substitute a new instrument with the same SI number (see paragraph 3.4.11 of Statutory Instrument Practice). A second instrument revoking and replacing this instrument is therefore being prepared as soon as practicable.

3.4 This instrument imposes fee increases above the rate of inflation. The Department has the following explanation.

3.5 The MHRA does not receive any central funding for the medicines element of its work. This is fully funded by fees paid by the industry. For medical devices regulation nearly all of the costs are publicly funded through a Service Level Agreement with DH although a small proportion of its funding comes from fees charged. The MHRA's operations are financed by means of a Government trading fund and the Agency must therefore ensure that its income is sufficient, taking one year with another, to meet its expenditure.

3.6 The fee increase is above the rate of inflation for several reasons:

- to cover essential unavoidable costs for the Agency in carrying out its regulatory functions (such as accommodation costs, increasing utilities costs, retention and recruitment of staff in assessing applications);
- to support the Agency's focus on improving service levels in terms of response times for handling applications;
- the devices fees (being increased by an overall 20%) have not been increased since 1997 and a cost assessment identified that these fees were not set at a rate sufficient to recover costs.

3.7 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. The Agency has a large number of different fees specific to different areas of work. Some fees are one-off capital fees (e.g. for a new licence application), some are charged for each time an activity takes place (e.g. fees for inspections or variations to existing licences), and others are annual fees that are intended to cover the costs of activity such as ongoing drug safety monitoring and enforcement. The individual fee levels vary greatly from £58 for an export certificate for a medicinal product, up to £89k for a licence application for a major new medicinal product. A rigorous costing exercise, which took place in 2005/2006 (to inform the fees proposals for April 2006) revealed greater discrepancies between costs and fees in some areas compared with others. Taking this costing exercise forward to 2007/2008, increases in individual fees for April 2007 vary from no increase at all to 88% (this increase relates to fees charged for voluntary pre-application meetings where the length of the meetings and the actual cost of time spent by highly qualified staff has now been fully quantified following the introduction of these meetings in recent years). Fees for medical devices regulatory work have not been increased since 1997 – the average increase for these fees are 30%.

3.8 The Agency assesses its fees and costs each year. Where there are likely to be future increases in fees in line with costs, the Agency is taking measures to deliver efficiencies.

4. Legislative background

4.1 This instrument amends: the Medicines (Products for Human Use–Fees) Regulations 1995 (SI 1995 No 1116 as amended); the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 (SI 1995 No 449 as amended); the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (SI 1994 No 105 as amended); and the Medical Devices Regulations 2002 (SI 2002 No 618 as amended). The instrument is made to increase the fees payable in accordance with the provisions of those regulations, to introduce a number of new fees and to change the rules governing when certain fees are payable.

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 negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health. It carries out the functions of the Ministers constituting the Licensing Authority (as described in section 1 of the Medicines Act 1968), in relation to the regulation of medicines for human use. It also carries out the functions of the Secretary of State, in relation to the regulation of medical devices . This instrument affects both the medicines and medical devices functions of the Agency..

7.2 The MHRA is financed by means of a Government trading fund and, as such, is fully funded for its medicines regulatory work by fees paid by the industry in connection with the manufacture, sale and supply of medicines. For medical devices regulation nearly all of the costs are publicly funded through a Service Level Agreement with Department of Health. 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. 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 around £3.1 million. 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. The total income estimated for MHRA in 2007/2008, taking into account the increased fees and anticipated volumes, is expected to be around £67 million.

7.5 All sectors of the pharmaceutical industry involved in the manufacture, sale and wholesale of medicinal products for humans use (around 3,000 organisations and companies in all), UK Notified and Conformity Assessment Bodies (7 in total) and sectors of the medical

device industry involved in carrying out clinical investigations for regulatory purposes (72 companies and organisations) in the UK are affected. All of these companies and organisations have been consulted during an 11 week period (12 weeks for devices fees) on the proposals to increase these fees Two full RIAs have been prepared (one for medicines and one for medical devices) and are 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. The industry fully supports the MHRA's work in relation to medicines and medical devices regulation but is concerned about the level of increase in the fees for medicines, particularly in relation to current service levels being experienced in the area of licensing for medicines. The MHRA has met directly with, and discussed these issues with some of the main industry associations and has worked closely with them during 2006/2007 to resolve the problems. Some improvements have been achieved. This will be built on in 2007/2008.

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 Two Regulatory Impact Assessments (one each for medicines and devices) are attached to this memorandum.

8.2 The impact on the public sector is minimal. The changes to fees mainly affect the private sector pharmaceutical industry and notified bodies in relation to medical devices. However, some NHS bodies, and academic research bodies will be affected by the increases in some fees.

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.