STATUTORY INSTRUMENTS

2004 No. 1157

FEES AND CHARGES

MEDICINES

The Medicines for Human Use (Clinical Trials Fees Amendments) Regulations 2004

Made - - - -	*19th April 2004*
Laid before Parliament	*19th April 2004*
Coming into force	*10th May 2004*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**a**) in relation to medicinal products(**b**), in exercise of the powers conferred upon him by the said section 2(2), and the Secretary of State, with the consent of the Treasury, in exercise of the powers conferred upon him by section 56(1) and (2) of the Finance Act 1973(**c**), and in exercise of all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Clinical Trials Fees Amendments) Regulations 2004 and shall come into force on 10th May 2004.

(2) In these Regulations, "the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**d**).

Amendment of regulation 2 of the General Fees Regulations

2.—(1) Regulation 2 of the General Fees Regulations (interpretation) is amended as follows.

(2) In paragraph (1)—

(a) after the definition of "the 1994 Regulations" insert the following definition—

> ""application", in relation to a clinical trial authorisation, means a request for authorisation to conduct a clinical trial made in accordance with regulation 17 of the Clinical Trials Regulations, and "applicant", in relation to such authorisation, means the person making the request;";

(b) in the definition of "change of ownership application"(**e**)—

(**a**) 1972 c.68.
(**b**) S.I. 1972/1811.
(**c**) 1973 c.51.
(**d**) S.I. 1995/1116; as amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, 2001/795, 2002/236 and 542, 2003/625 and 2321, and 2004/666.
(**e**) The definition of "change of ownership" was substituted by regulation 2 of S.I. 1996/683.

(i) in paragraph (a), after sub-paragraph (i) insert—

"(ia) a manufacturing authorisation for activities in respect of which another person holds a manufacturing authorisation;",

(ii) in paragraph (b), after "marketing authorization" insert ", manufacturing authorisation",

(iii) in paragraph (c), after "marketing authorization" insert ", manufacturing authorisation";

(c) after the definition of "change of ownership application" insert the following definitions—

""clinical trial" means any investigation in human subjects, other than a non-interventional trial, intended—

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,

(b) to identify any adverse reactions to one or more such products, or

(c) to study absorption, distribution, metabolism and excretion of one or more such products,

with the object of ascertaining the safety or efficacy of those products;

"clinical trial authorisation" means authorisation of the conduct of a clinical trial—

(a) by the licensing authority in accordance with regulation 18, 19 or 20 of the Clinical Trials Regulations, or

(b) which is treated as having been given by the licensing authority by virtue of Schedule 12 to those Regulations;

"Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004(**a**);";

(d) for the definition of "contract laboratory"(**b**) insert the following definitions—

""conditions and principles of good clinical practice" means the conditions and principles specified in Schedule 1 to the Clinical Trials Regulations;

"contract laboratory" means a laboratory carrying out the examinations and tests referred to in—

(a) paragraph 5A(2) of Schedule 2 or paragraph 8(3)(a) of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**c**), and

(b) Article 11(1) of Directive 2003/94/EC,

on behalf of the holder of a manufacturing authorisation, manufacturer's licence or wholesale dealer's licence, pursuant to Article 11(2) of that Directive and Article 20(b) of the 2001 Directive;";

(e) after the definition of "fee period" insert the following definition—

""holder", in relation to a clinical trial authorisation, means—

(a) in the case of authorisation treated as having been given by the licensing authority by virtue of Schedule 12 to the Clinical Trials Regulations, the person acting as sponsor of the clinical trial for the purposes of those Regulations, or

(b) in any other case, person who made the request for that authorisation;";

(f) after the definition of "manufacturer's licence" insert the following definition—

""manufacturing authorisation" means a manufacturing authorisation granted for the purposes of regulation 36 of the Clinical Trials Regulations;";

(**a**) S.I. 2004/1031.
(**b**) The definition of "contract laboratory" was inserted by S.I. 2004/666.
(**c**) S.I. 1971/972; relevant amending instruments are S.I. 1977/1053 and 1992/2846.

(g) in the definition of "medicinal product", after "Part II of the Act" insert "or the Clinical Trials Regulations"; and

(h) in the definition of "relevant fee period", after "authorization" insert ", clinical trial authorisation, manufacturing authorisation".

(3) After paragraph (1) insert the following paragraph—

"(1A) For the purposes of these Regulations, a clinical trial authorisation is in force if the licensing authority has not—

(a) received notification of the conclusion of the clinical trial to which the authorisation relates, in accordance with regulation 27 of the Clinical Trials Regulations, or

(b) suspended or terminated the trial at all sites at which that clinical trial was conducted, in accordance with regulation 31 of those Regulations.".

Amendment of Part II of the General Fees Regulations

3.—(1) Part II of the General Fees Regulations (capital fees for applications for authorizations, licences or certificates and for associated inspections) is amended as follows.

(2) In regulation 4 (applications for authorizations, licences or certificates), for "a wholesale dealer's licence or a clinical trial certificate" substitute "a manufacturing authorisation, a wholesale dealer's licence or a clinical trial authorisation".

(3) In regulation 5 (inspections in connection with multiple applications for authorizations or licences)—

(a) in paragraph (a), after "marketing authorization" insert " or clinical trial authorisation,"; and

(b) in paragraph (b), after "manufacturer's licence" insert "or manufacturing authorisation,".

Amendment of Part III of the General Fees Regulations

4.—(1) Part III of the General Fees Regulations (capital fees for applications for variations of authorizations, licences or certificates and for associated inspections) is amended as follows.

(2) In regulation 7 (variations of authorizations, licences and certificates), in paragraph (1), for sub-paragraph (c) substitute—

"(c) under regulation 44 of the Clinical Trials Regulations for the variation of a manufacturing authorisation,".

(3) After regulation 7 of the General Fees Regulations, insert the following regulation—

"Amendments to clinical trial authorisations

7A.—(1) A person who sends a valid notice of amendment under regulation 24 of the Clinical Trials Regulations relating to amendment of the dossier accompanying a request for authorisation in accordance with paragraph 11 of Schedule 3 to those Regulations shall pay the fees mentioned in paragraph (2).

(2) The fees referred to in paragraph (1) are—

(a) the fee prescribed in paragraph 11 of Part III of Schedule 1 in connection with that amendment; and

(b) in respect of any inspection of a description referred to in paragraph 1 of Schedule 2 made in connection with the application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.".

(4) Regulation 8 (inspections in connection with multiple applications for variations of authorizations and licences) shall be renumbered as paragraph (1) of that regulation and—

(a) in paragraph (1)—

(i) after "applicant for a variation" insert "or amendment",

(ii) in paragraph (a), after "marketing authorization" insert "or clinical trial authorisation,", and

(iii) in paragraph (b), after "manufacturer's licence" insert "or manufacturing authorisation,"; and

(b) after paragraph (1) insert the following paragraph—

"(2) In paragraph (1), the reference to an applicant for an amendment to a clinical trial authorisation is a reference to a person sending a valid notice of amendment as mentioned in regulation 7A(1).".

(5) In regulation 9 (applications for multiple variations)—

(a) in paragraph (1), for "licence or certificate" substitute "manufacturing authorisation or licence"; and

(b) in paragraph (2), for "licence or certificate" substitute "manufacturing authorisation or licence".

Amendment of Part IV of the General Fees Regulations

5.—(1) Part IV of the General Fees Regulations (capital fees for renewals of clinical trial certificates and for certain manufacturer's licences and associated inspections) is amended as follows.

(2) Regulation 10 (renewals of clinical trial certificates) is omitted.

(3) In regulation 12 (renewals in terms which are not identical to the existing authorization, licence or certificate)—

(a) for ", a wholesale dealer's licence or a clinical trial certificate" substitute "or a wholesale dealer's licence"; and

(b) for ", licence or certificate", in both places those words appear, substitute "or licence".

Amendment of Part V of the General Fees Regulations

6.—(1) Part V of the General Fees Regulations (fees for inspections made during the currency of a marketing authorization or licence) shall be amended as follows.

(2) In regulation 13 (fees for inspections)—

(a) in paragraph (1)—

(i) after "marketing authorization," insert "a clinical trial authorisation, a manufacturing authorisation,", and

(ii) after "otherwise payable under" insert "regulation 13A or";

(b) in paragraph (2)—

(i) after "currency of" insert "a manufacturing authorisation,", and

(ii) for "that licence" substitute "that authorisation or licence; and

(c) in paragraph (3), after "marketing authorization", in each places those words appear, insert "or clinical trial authorisation".

(3) After regulation 13, insert the following regulation—

"Fees for inspections relating to good clinical practice in clinical trials

13A. Subject to regulations 19 and 23, a fee in accordance with paragraphs 7 and 8 of Schedule 2 shall be payable by a person in respect of any inspection of one or more sites for the purpose of ascertaining whether that person—

(a) is—

(i) conducting, or has conducted, a clinical trial, or

(ii) performing, or has performed, the functions of a sponsor of a clinical trial,

in accordance with the conditions and principles of good clinical practice, pursuant to regulation 28(1) of the Clinical Trials Regulations; or

(b) has put and kept in place arrangements for the purpose of ensuring that with regard to a clinical trial the conditions and principles of good clinical practice are satisfied or adhered to, pursuant to regulation 28(2) of those Regulations.".

Amendment of Part VI General Fees Regulations

7.—(1) Part VI of the General Fees Regulations (periodic fees for marketing authorizations and licences) shall be amended as follows

(2) In regulation 14 (periodic fees)—

(a) in paragraph (1)—

(i) after "(other than a Community marketing authorization)," insert "a manufacturing authorisation,", and

(ii) for "authorization or licence" substitute "authorization, authorisation or licence"; and

(b) in paragraph (6)—

(i) after "period during which" insert "a manufacturing authorisation,",

(ii) in sub-paragraph (a), for "licence" substitute "authorisation or licence", and

(iii) in sub-paragraph (b), after "in connection with the" insert "manufacturing authorisation or".

(3) After regulation 14, insert the following regulation—

"Periodic fees for clinical trial authorisations

14A.—(1) Subject to paragraphs (3) to (5) and to regulations 19 and 23, there shall be payable by the holder of a clinical trial authorisation the fee in connection with the holding of that authorisation in respect of each fee period during any part of which the authorisation is in force.

(2) The periodic fee shall be the fee prescribed in paragraph 10 of Part III of Schedule 1.

(3) Where a person holds more than one clinical trial authorisation in relation to clinical trials in which the same medicinal product is being tested, the authorisations shall be treated for the purposes of paragraph (1) as if they were one clinical trial authorisation and only one periodic fee in respect of each relevant fee period shall be payable in connection with the holding of such authorisations.

(4) No periodic fee is payable in respect of the fee period during which the clinical trial to which the authorisation relates was authorised by the licensing authority in accordance with regulation 18, 19 or 20 of the Clinical Trials Regulations.

(5) In relation to a clinical trial which is treated as being authorised by the licensing authority by virtue of Schedule 12 to the Clinical Trials Regulations, no periodic fee shall be payable in respect of the fee period ending on 31st March 2005.".

Amendment of Part VII of the General Fees Regulations

8.—(1) Part VII of the General Fees Regulations (administration) is amended as follows.

(2) In regulation 19 (adjustment, waiver, reduction or refund of fees), in paragraph (1), for "authorization, licence or certificate", in both places those words appear, substitute "authorization, authorisation or licence".

(3) In regulation 20 (suspension of licence and certificates), omit "or a clinical trial certificate" and "or certificate".

Amendment of Schedule 1 to the General Fees Regulations

9.—(1) Schedule 1 to the General Fees Regulations (capital fees for applications for, and variations to, marketing authorizations, licences and certificates) is amended as follows.

(2) In Part I of the Schedule (interpretation), in paragraph 1—

(a) after "decentralised incoming application" insert the following definition—

""EC marketing authorization" means—

(a) a marketing authorization, or

(b) an authorization issued by the competent authorities of an EEA State other than the United Kingdom for the purposes of Article 6 of the 2001 Directive;"; and

(b) after "new excipient" insert the following definitions—

""Phase I trial" means a clinical trial to study the pharmacology of a medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial;

"Phase II or Phase III trial" means a clinical trial, other than a Phase I trial, where the medicinal product being tested—

(a) does not have an EC marketing authorization; or

(b) has an EC marketing authorization, but—

(i) there has been a change—

(aa) to the process of manufacture of the product or its active ingredient, or

(bb) of manufacturer of that product or substance, or

(ii) the product is to be used in the trial other than in accordance with the terms of the summary of product characteristics under that authorization;

"Phase IV trial" means a clinical trial other than a Phase I trial or a Phase II or Phase III trial;".

(3) In Part II of the Schedule (capital fees for applications for authorizations, licences and certificates)—

(a) in paragraph 5, in sub-paragraph (1), after "manufacturer's licence" insert "or a manufacturing authorisation"; and

(b) for paragraph 7 substitute—

"Clinical trial authorisations

7.—(1) Subject to sub-paragraphs (3) and (4), the fee payable under regulation 4(a) in connection with an application for a clinical trial authorisation in relation to a clinical trial of a kind described in column 1 of the following Table shall be the fee specified in the corresponding entry in column 2 of that Table.

Table

Column 1 *Kind of clinical trial*	*Column 2* *Fee payable*
Phase I trial	£610
Phase II or Phase III trial where the medicinal product being tested is unknown to the licensing authority	£2700
Phase II or Phase III trial where the product being tested is known to the licensing authority	£2250
Phase IV trial	£140

(2) For the purposes of that Table, a medicinal product is known to the licensing authority if—

(a) the product has an EC marketing authorization; or

(b) the product does not have an EC marketing authorization, but where—

(i) another pharmaceutical form or strength of that product has an EC marketing authorization and the medicinal product is supplied for the purposes of the clinical trial by the holder of that authorization,

(ii) another medicinal product containing the same active substance has an EC marketing authorization and the medicinal product is supplied for the purposes of the clinical trial by the manufacturer of that other product, or

(iii) a clinical trial in which that product is, or was, being tested or used has been authorised by the competent authority of an EEA State other than the United Kingdom in accordance with Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use(**a**).

(3) Where the application is in relation to a clinical trial in which the medicinal products being tested or used are the same as those being tested or used in a clinical trial—

(a) in respect of which the applicant made a request for authorisation; and

(b) which has been authorised by the licensing authority for the purposes of the Clinical Trials Regulations,

the fee payable in connection with that application shall be £100.

(4) Where—

(a) the medicinal product to be tested in the clinical trial to which the application relates has been used in another clinical trial that has been authorised, or is to be treated as having been authorised, by the licensing authority for the purposes of the Clinical Trials Regulations; and

(b) the sponsor of that other trial authorises the licensing authority to refer to the dossier submitted in relation to that product in accordance with paragraph 11 of Schedule 3 to those Regulations,

the fee payable in connection with that application shall be £140.".

(**a**) OJ No. L121, 1.5.2001, p.34.

(4) In Part III of the Schedule (capital fees for applications for variations of authorizations, licences and certificates)—

(a) in paragraph 7—

(i) after "7(1)(b)" insert "or (c)", and

(ii) after "variation of" insert "a manufacturing authorisation or";

(b) in paragraph 8—

(i) after "7(1)(b)" insert "or (c)",

(ii) after "variation of" insert "a manufacturing authorisation or", and

(iii) for "the licence" substitute "the authorisation or licence";

(c) for paragraph 11 substitute—

"Clinical trial authorisations

11.—(1) The fee payable under regulation 7A(1) in connection with a notice of amendment relating to amendment to the dossier accompanying a request for authorisation to conduct a clinical trial shall be—

(a) if the amendments relate to one of the parts of the dossier specified in sub-paragraph (2) only, £100;

(b) if the amendments relate to two parts of the dossier specified in sub-paragraph (2) only, £200; or

(c) if the amendments relate to all three parts of the dossier specified in sub-paragraph (2), £300.

(2) The parts of the dossier specified in paragraph (1) are—

(a) the part containing the summaries of the chemical, pharmaceutical and biological data relating to the medicinal product tested or used in the trial;

(b) the part containing the summaries of the non-clinical pharmacology and toxicology data on that product; and

(c) the part containing the summaries of the available data from previous clinical trials of, and human experience with, that product."; and

(d) omit paragraph 12.

Amendment of Schedule 2 to the General Fees Regulations

10. In Schedule 2 to the General Fees Regulations (fees for inspections) after paragraph 6 insert the following paragraphs—

"7.—(1) Subject to paragraph 8, the fee payable under regulation 13A(1) by a person in respect of any inspection of one or more sites for the purpose of ascertaining whether that person—

(a) is—

(i) conducting, or has conducted, a clinical trial, or

(ii) performing, or has performed, the functions of a sponsor of a clinical trial,

in accordance with the conditions and principles of good clinical practice, pursuant to regulation 28(1) of the Clinical Trials Regulations; or

(b) has put and kept in place arrangements for the purpose of ensuring that with regard to a clinical trial the conditions and principles of good clinical practice are satisfied or adhered to, pursuant to regulation 28(2) of those Regulations,

shall be calculated as specified in sub-paragraphs (2) to (4).

(2) For each category of activity relevant to compliance with good clinical practice described in column (1) of the following Table which is assessed for compliance at a site

inspected as part of that inspection, the points specified in the corresponding entry in column 2 of that Table shall be allocated.

Table

Column 1 *Category of GCP activity*	*Column 2* *Points*
Archiving	1
Project management	3
Quality system	2
Essential documents	3
Contracts and agreements	2
Training	2
Computer systems	3
Data management	3
Statistics	2
Regulatory affairs	1
Investigational medicinal product management	2
Monitoring	3
Pharmacovigilance	2
Reporting	1

(3) The points allocated for each category of activity assessed at a site shall be added to give a total for that site and the points for each site visited as part of that inspection shall be added to give a total for that inspection.

(4) The fee payable shall be—

(a) where the total points for an inspection are less than 10, £3,000,

(b) where the total points for an inspection are more than 9 and less than 16, £5,000,

(c) where the total points for an inspection are more than 15 and less than 26, £10,000, and

(d) where the total points for an inspection are more than 25, £15,000,

except that where more than 2 sites are visited as part of an inspection an additional fee of £3,000 shall be payable for each extra site visited.

8. The fee payable in respect of an inspection where a site inspected is outside the United Kingdom shall be increased by an amount equal to the travelling and subsistence costs of the inspector relating to the inspection and any additional costs (such as interpreters' fees) reasonably incurred by him in respect of that inspection as a result of its being at a site outside the United Kingdom.".

Amendment of Schedule 3 to the General Fees Regulations

11. In Part III of Schedule 3 to the General Fees Regulations (periodic fees for marketing authorizations and licences)—

(a) after "manufacturer's licence" insert "or manufacturing authorisation"; and

(b) after paragraph 9 insert the following paragraph—

"Clinical trial authorisations

10. The fee payable under regulation 14A(2) in connection with the holding of a clinical trial authorisation shall be £200.".

Amendment of Schedule 4 to the General Fees Regulations

12. In Schedule 4 to the General Fees Regulations (time for payment of capital fees—applications made by small companies)—

(a) in paragraph 5, after "manufacturer's licence" insert ", manufacturing authorisation"; and

(b) in paragraph 6, after "manufacturer's licence" insert ", manufacturing authorisation".

Amendment of Schedule 5 to the General Fees Regulations

13.—(1) Schedule 5 to the General Fees Regulations (waiver, reduction or refund of capital fees) is amended as follows.

(2) In paragraph 3—

(a) in sub-paragraph (1)—

(i) for "or a clinical trial certificate, or for the renewal of a clinical trial certificate" substitute ", an application for a clinical trial authorisation or a notice of amendment to a clinical trial authorisation",

(ii) for "7(1) or 10" substitute "7(1) or 7A(1)",

(iii) after "that application" substitute "or notice", and

(iv) in paragraph (a), after "application" insert "or notice"; and

(b) in sub-paragraph (3)—

(i) for "or a clinical trial certificate, or for the renewal of a clinical trial certificate" substitute ", an application for a clinical trial authorisation or a notice of amendment to a clinical trial authorisation",

(ii) for "7(1) or 10" substitute "7(1) or 7A(1)", and

(iii) after "that application" insert "or notice".

(3) In paragraph 4, after "variation to," insert "a manufacturing authorisation or".

(4) In paragraph 4A, for "or a clinical trial certificate" substitute "or an application for a clinical trial authorisation".

(5) Paragraph (5) is renumbered as sub-paragraph (1) of that paragraph and—

(a) in that sub-paragraph—

(i) after "manufacturer's licence" insert "or manufacturing authorisation", and

(ii) after "both such licences" insert ", or that authorisation and that licence"; and

(b) after that sub-paragraph, insert the following sub-paragraph—

"(2) Where the same site is inspected at the same time in connection with applications for the grant or variation of both a manufacturing authorisation and a manufacturer's licence, or during the currency of that authorisation and that licence, the fee otherwise payable under these Regulations in respect of the inspection relating to the manufacturer's licence or the fee otherwise payable in respect of the manufacturing authorisation, whichever is lower, shall be waived.".

(6) After paragraph 7, insert the following paragraph—

"**8.**—(1) In relation to an application for a clinical trial authorisation in relation to a Phase I trial or a Phase II or Phase III trial, the fee payable in respect of such an application may be reduced in accordance with the following paragraphs.

(2) Where the licensing authority is satisfied that the investigational medicinal product dossier submitted in accordance with paragraph 11 of Schedule 3 to the Clinical Trials Regulations does not require a full medical, scientific or pharmaceutical assessment, the fee may be reduced by an amount which the authority considers to be the cost of the assessment work which is not required.

(3) The fee payable may not be reduced below £100.

(4) Where the fee has been reduced by the licensing authority but the applicant has paid the full fee, the amount by which the fee has been reduced shall be refunded to the applicant.".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

14th April 2004

We consent,

Nick Ainger
Jim Murphy
Two of the Lords Commissioners of Her Majesty's Treasury

19th April 2004

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations"). The General Fees Regulations make provision for the fees payable in relation to marketing authorizations, licences and certificates in respect of medicinal products for human use. These Regulations amend the General Fees Regulations to provide for fees in respect of authorisations and inspections relating to clinical trials of such products.

Regulation 2 amends regulation 2 of the General Fees Regulations (interpretation).

Regulations 3, 4, 8, 9, 12 and 13 amend the General Fees Regulations to make provision for capital fees for: requests for authorisations of clinical trials given by the licensing authority under the Medicines for Human Use (Clinical Trials) Regulations 2004 ("clinical trial authorisations"); certain notices of amendment of such authorisations; applications for authorisation to manufacture medicinal products for a clinical trial, granted by the licensing authority under those Regulations ("manufacturing authorisations"); and applications for the variation of such authorisations.

Regulations 6 and 10 amend the General Fees Regulations to make provision for fees for inspections relating to manufacturing sites connected with manufacturing authorisations or clinical trial authorisations, and for inspections of sites for the purposes of ascertaining whether clinical trials are being conducted in accordance with the conditions and principles of good clinical practice.

Regulations 7 and 11 amend the General Fees Regulations to make provision for periodic fees for manufacturing authorisations and clinical trial authorisations.

Regulations 3 to 5, 8, 9 and 13 also make consequential amendments to remove references to fees relating to clinical trial certificates issued under section 31 of the Medicines Act 1968; that provision is repealed by the Medicines for Human Use (Clinical Trials) Regulations 2004.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and a copy has been placed in the libraries of both Houses of Parliament.

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