SCHEDULE 1

Article 2

FUNDED OPERATIONS

1. All the operations of that part of the Department of Health known from 1st April 2003 as the Medicines and Healthcare Products Regulatory Agency carried out in connection with the following: —

(a) the functions of the Health Ministers, the Ministers, the appropriate body or the licensing authority under—

(i) the Medicines Acts of 1968 and 1971(**1**) and secondary legislation under those Acts, and

(ii) any legislation of the European Communities or their institutions relating to medicinal products, and related implementing legislation;

(b) the functions of the Secretary of State relating to the application of the principles of good laboratory practice and the verification of their application for tests on substances and to the inspection and verification of good laboratory practice as laid down in Council Directive 87/18/EEC of 18th December 1986(**2**) as amended and Council Directive 88/320/EEC of 9th June 1988(**3**) as amended and related implementing legislation, and as arising out of the United Kingdom's membership of the Organisation for Economic Co-operation and Development;

(c) the functions of the Secretary of State—

(i) under the Medical Devices Regulations 2002(**4**) and the Medical Devices Directives,

(ii) under the Clinical Thermometers (EEC Requirements) Regulations 1993(**5**),

(iii) otherwise in connection with the safe use of medical devices or similar devices;

(d) the functions of the Secretary of State under any legislation of the European Communities or their institutions relating to general product safety, and related implementing legislation in so far as the legislation relates to medicinal products or medical devices or similar products or devices;

(e) the functions of the United Kingdom authorities relating to medicinal products, medical devices or similar products or devices under international obligations or in connection with Association Agreements or Mutual Recognition Agreements or in connection with any activities of the European Communities or any of their institutions;

(f) the provision of services relating to or in connection with public health, medicinal products, medical devices or similar products or devices to meet the needs of customers in the United Kingdom, in Europe or world-wide including:

(i) assistance to other regulatory authorities, other Government departments or agencies, or public bodies,

(ii) advisory, information, education or training services,

(iii) the collection, processing, analysis or provision of data,

(iv) the inspection or accreditation of tissue banks,

(v) assessment of devices or components of devices,

(vi) the sale of reference substances,

(**1**) 1971 c. 69.
(**2**) OJNo. L15, 17.1.87, p. 29; amended by Commission Directive 1999/11/EC (OJ No. L77, 23.3.1999, p. 8).
(**3**) OJ No. L145, 11.6.88, p. 35; amended by Commission Directive 90/18/EEC (OJ No. L11, 13.1.90, p. 30) and Commission Directive 1999/12/EC (OJ No. L77, 23.3.1999, p. 22).
(**4**) S.I.2002/618.
(**5**) S.I. 1993/2360.

(vii) the sale of publications.

2. Any operations carried on in connection with any proposed legislation or the provision and dissemination of information relating to the functions described in paragraph 1.

3. Any operations which are incidental, conducive or are otherwise ancillary to the operations described in paragraphs 1 and 2.