HOUSE OF LORDS

Merits of Statutory Instruments Committee

16th Report of Session 2008-09

Drawing special attention to:

Medicines for Human Use (Miscellaneous Amendments) Regulations 2009

Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009

National Health Service (Charges) (Amendments Relating to Pandemic Influenza) Regulations 2009

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The Select Committee on the Merits of Statutory Instruments

The Committee has the following terms of reference:

(1) The Committee shall, subject to the exceptions in paragraph (2), consider—

(a) every instrument (whether or not a statutory instrument), or draft of an instrument, which is laid before each House of Parliament and upon which proceedings may be, or might have been, taken in either House of Parliament under an Act of Parliament;

(b) every proposal which is in the form of a draft of such an instrument and is laid before each House of Parliament under an Act of Parliament,

with a view to determining whether or not the special attention of the House should be drawn to it on any of the grounds specified in paragraph (3).

(2) The exceptions are—

(a) remedial orders, and draft remedial orders, under section 10 of the Human Rights Act 1998;

(b) draft orders under sections 14 and 18 of the Legislative and Regulatory Reform Act 2006, and subordinate provisions orders made or proposed to be made under the Regulatory Reform Act 2001;

(c) Measures under the Church of England Assembly (Powers) Act 1919 and instruments made, and drafts of instruments to be made, under them.

(3) The grounds on which an instrument, draft or proposal may be drawn to the special attention of the House are—

(a) that it is politically or legally important or gives rise to issues of public policy likely to be of interest to the House;

(b) that it may be inappropriate in view of changed circumstances since the enactment of the parent Act;

(c) that it may inappropriately implement European Union legislation;

(d) that it may imperfectly achieve its policy objectives.

(4) The Committee shall also consider such other general matters relating to the effective scrutiny of the merits of statutory instruments and arising from the performance of its functions under paragraphs (1) to (3) as the Committee considers appropriate, except matters within the orders of reference of the Joint Committee on Statutory Instruments.

Members

The members of the Committee are:

Rt Hon. the Baroness Butler-Sloss GBE
The Lord Crisp KCB
The Baroness Deech DBE
The Viscount Eccles CBE
The Lord Filkin CBE (*Chairman*)
The Lord Hart of Chilton
The Lord James of Blackheath CBE
The Lord Lucas
The Baroness Maddock
The Lord Rosser
The Baroness Thomas of Winchester

Registered interests

Members' registered interests may be examined in the online Register of Lords' Interests at www.publications.parliament.uk/pa/ld/ldreg.htm. The Register may also be inspected in the House of Lords Record Office and is available for purchase from the Stationery Office.

Publications

The Committee's Reports are published by the Stationery Office by Order of the House in hard copy and on the internet at www.parliament.uk/parliamentary_committees/merits.cfm

Contacts

If you have a query about the Committee or its work, please contact the Clerk of the Merits of Statutory Instruments Committee, Delegated Legislation Office, House of Lords, London SW1A 0PW; telephone 020-7219 8821; fax 020-7219 2571; email merits@parliament.uk. The Committee's website, www.parliament.uk, has guidance for the public on how to contact the Committee if you have a concern or opinion about any new item of secondary legislation.

Statutory instruments

The Government's Office of Public Sector Information publishes statutory instruments on the internet at www.opsi.gov.uk/stat.htm, together with an explanatory memorandum (a short, plain-English explanation of what the instrument does) for each instrument.

Sixteenth Report

INSTRUMENTS DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

The Committee has considered the following instruments and has determined that the special attention of the House should be drawn to them on the grounds specified.

Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (SI 2009/1164)

Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (SI 2009/1165)

National Health Service (Charges) (Amendments Relating to Pandemic Influenza) Regulations 2009 (SI 2009/1166)

Summary: These are the first of a number of statutory instruments that set out specific contingency provisions for use in the case of a flu pandemic. In the event of a pandemic it is likely that a vastly increased number of people will contact NHS services for advice, diagnosis, treatment and medicines, in particular antivirals. These measures set out to streamline regimes so that access to both antivirals and other medicines can be maintained at a time when access to health professionals may be limited.

These Regulations are drawn to the special attention of the House on the ground that they give rise to issues of public policy likely to be of interest to the House.

1. The Department of Health (DH) has laid these Regulations under the Medicines Act 1968, the National Health Service Act 2006 and the European Communities Act 1972, together with a combined Explanatory Memorandum (EM) and an Impact Assessment (IA). We note that despite the speed with which these measures have been brought forward, most have been subject to consultation with a wide range of professional bodies, and that the 40 responses viewed the proposals as an appropriate balance between safeguarding the public and meeting the circumstances of a pandemic.

2. Although these instruments were brought into effect the day after they were laid, they are principally enabling measures and the key provisions will only be brought into full operation if a pandemic is declared, or Ministers judge that the pressure on the health service is such that emergency measures are required. DH say that the measures will not be automatically triggered if the World Health Organisation (WHO) raise the alert to phase 6 (pandemic): the Health Minister will need to issue a direction to health service bodies in the UK to put the measures into effect.

3. These are the first of a number of statutory instruments that may be issued to set out specific contingency provisions for use in the case of a pandemic. While the provisions primarily aim to cover the current outbreak of swine flu, these instruments potentially cover other serious pandemic diseases.

4. The majority of the provisions in these instruments build on existing contingency measures and are not completely novel. In the event of a pandemic it is likely that a vastly increased number of people will contact NHS services for advice, diagnosis, treatment and medicines; in particular antivirals. These measures set out to streamline regimes so that access to both antivirals and other medicines can be maintained at a time when access to health professionals may be limited.

5. The **Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (SI 2009/1164)** allow for the wholesale distribution and use of an antiviral medicine in solution for children under one year of age during a pandemic that is based on a powder not fully authorised for use in the UK in this form. The powder (oseltamivir) is an active pharmaceutical ingredient used in other products that are licensed and currently available in the UK and in the European Union including the various forms of Tamiflu. Tamiflu is not licensed for use in children under one year of age. There is published clinical data to support the use of oseltamivir in that age group if the benefits outweigh the risks, recognising that there is no licensed product available. Therefore in developing a response to an emerging pandemic, it was decided by the DH to purchase supplies of oseltamivir powder from the manufacturer and to designate certain licensed hospital pharmacy manufacturing units to produce the relevant solution for children aged under one year who are assessed as being in need of it by a doctor.

6. This view is supported by the European Medicines Agency, which announced on 8 May that their Committee on Medicinal Products for Human Use had concluded that during an officially declared influenza H1N1 pandemic the benefits of the use of Tamiflu outweigh its risks in the treatment of children in that age group but, because there is less evidence to support the use of Tamiflu for the prevention of influenza, doctors should carefully consider the benefits and risks for each patient. The Centre for Disease Control in the United States has issued similar advice.

7. These regulations also temporarily simplify labelling procedures for that solution. In addition the Regulations require safety concerns raised during clinical trials of medicines to be notified to the licensing authority and ethics committee "as soon as possible" rather than the usual 3 days.

8. The **Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (SI 2009/1165)** is more complicated than the other instruments since it contains a combination of permanent and pandemic-only measures. As well as relaxing provisions during a pandemic, it permanently increases from 5 days to a maximum of 30 days the period for which pharmacists can issue an emergency supply of medicine without prescription, for example to someone, such as a diabetic, who relies on a daily dose of medication but who has lost or finished their current supply. This is a measure that DH has been considering for some time, and it is convenient to bring it in now in parallel with the similar pandemic measure which aims to reduce the potential burden on GPs and pharmacists by lengthening the period for which such medication can be issued and therefore decrease the demand for non-urgent patient appointments during a pandemic. Another permanent change also rectifies an omission, to include dentists in the list of those prescribers whose directions may be taken into account by a pharmacist under these emergency supply provisions.

9. In addition, as a pandemic-only measure, this Order would reduce the requirements on the pharmacist to interview the patient himself about his medication, since the patient may need his routine medicines collecting by someone else if he has flu in addition to the condition for which he is normally treated. The pharmacist however will still need to satisfy himself that the person who is to be treated with the prescription-only medicine has been prescribed that medicine before and that the dosage of the medicine is appropriate for that person. The Department has issued a protocol to provide guidelines for the pharmacist and the measure does not apply to certain controlled drugs. This temporary relaxation of requirements aims to facilitate the supply of all medicines during a pandemic, i.e. not just anti-flu medicine, in order to free up GPs' time to deal with more urgent cases and to recognise that health professionals able to prescribe medicines may themselves catch the flu and be in shorter supply than usual.

10. Under the **National Health Service (Charges) (Amendments relating to Pandemic Influenza) Regulations 2009 (SI 2009/1166)** overseas visitors who need to be treated for pandemic flu while in the UK will not be charged for antiviral medicine or allied hospital treatment. This is a measure to combat the spread of the disease but would only apply for the duration of the declared pandemic.

INSTRUMENTS NOT DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

The Committee has considered the instruments set out below and has determined that the special attention of the House need not be drawn to them.

Draft Instruments requiring affirmative approval

Chilterns Area of Outstanding Natural Beauty (Establishment of Conservation Board) (Amendment) Order 2009

Cotswolds Area of Outstanding Natural Beauty (Establishment of Conservation Board) (Amendment) Order 2009

Instruments subject to annulment

SI 2009/831 Armed Forces (Terms of Service) (Amendment) Regulations 2009

SI 2009/832 Armed Forces (Discharge and Transfer to the Reserve Forces) Regulations 2009

SI 2009/833 Armed Forces (Forfeiture of Service) Regulations 2009

SI 2009/1021 First-tier Tribunal and Upper Tribunal (Chambers) (Amendment No. 2) Order 2009

SI 2009/1059 Armed Forces Act 2006 (Transitional Provisions etc) Order 2009

SI 2009/1060 Charitable Institutions (Fund-Raising) (Amendment) Regulations 2009

SI 2009/1085 Company and Business Names (Miscellaneous Provisions) Regulations 2009

SI 2009/1089 Armed Forces (Terms of Service) (Amendment) (No. 2) Regulations 2009

SI 2009/1090 Armed Forces (Forfeiture of Service) (No. 2) Regulations 2009

SI 2009/1091 Armed Forces (Discharge and Transfer to the Reserve Forces) (No. 2) Regulations 2009

SI 2009/1093 Armed Forces (Service of Process in Maintenance Proceedings) Regulations 2009

SI 2009/1094 Armed Forces (Prescribed Air Navigation Order Offences) Order 2009

SI 2009/1096 Service Custody and Service of Relevant Sentences Rules 2009

SI 2009/1097 Armed Forces (Custody Without Charge) Regulations 2009

SI 2009/1098 Armed Forces (Custody Proceedings) Rules 2009

SI 2009/1107 Armed Forces (Protection of Children of Service Families) Regulations 2009

SI 2009/1108 Armed Forces (Evidence of Illegal Absence and Transfer to Service Custody) Regulations 2009

SI 2009/1109 Armed Forces (Forfeitures and Deductions) Regulations 2009

SI 2009/1110 Armed Forces (Warrants of Arrest for Service Offences) Rules 2009

SI 2009/1111 Reserve Forces (Evidence in Proceedings before Civil Courts) Regulations 2009

SI 2009/1112 Armed Forces (Evidence in Proceedings before Civilian Courts) Regulations 2009

SI 2009/1114 Upper Tribunal (Lands Chamber) Fees Order 2009

SI 2009/1118 European Parliamentary Election Petition (Amendment) Rules 2009

SI 2009/1119 Animal By-Products (Amendment) Regulations 2009