

**2003 No. 3309**

**MEDICINES**

**The Animal Test Certificates (Revocation) Regulations  
2003**

*Made* - - - - - *18th December 2003*

*Laid before Parliament* *19th December 2003*

*Coming into force* - - *12th January 2004*

The Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development(a), acting jointly in exercise of the powers conferred by sections 36(1), 38(3) (as read with section 36(1)), 47(1), 85(1) and (4), 86(1), 91(2) and (3) and 129(1) and (5) of the Medicines Act 1968(b), and now vested in them, and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations in accordance with section 129(6) of that Act, make the following Regulations:

**Title and commencement**

1. These Regulations may be cited as the Animal Test Certificates (Revocation) Regulations 2003 and shall come into force on 12th January 2004.

**Revocation of the Animal Test Certificates Regulations 1996**

2. The Animal Test Certificates Regulations 1996(c) are revoked.

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(a) “The Ministers” are empowered under the recited sections of the Medicines Act 1968 to make these Regulations. “The Ministers” is defined in section 1 of that Act. Currently, these are—

- (i) the Secretary of State (by virtue of article 2(2) of, and paragraph 1 of the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (SI 1999/3142), and additionally in respect of Wales, the earlier Transfer of Functions (Wales) (No. 1) Order (SI 1978/272); and of article 3(1)(c) and (7) of and paragraph 15 of Schedule 1 to the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (SI 2002/794)); and
- (ii) the Northern Ireland Departments of Health, Social Services and Public Safety and of Agriculture and Rural Development. See paragraph 4(1)(b) of the Schedule to the Northern Ireland Act 2000 (c. 1), which has effect during suspension: this paragraph provides that the functions of a Northern Ireland Minister who was in charge of a Northern Ireland Department immediately before the coming into force of section 1 of the Act may be discharged by that Department, subject, according to paragraph 4(1)(f) of the Schedule, to the direction and control of the Secretary of State. Prior to the most recent occasion of the coming into force of section 1 of the Northern Ireland Act 2000 (as a consequence of the Northern Ireland Act (Suspension of Devolved Government) Order 2002 (SI 2002/2574)), the Ministers of these two Northern Ireland Departments exercised the relevant functions by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) and article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (SI 1999/283(N.I. 1)).

(b) 1968, c. 67.

(c) SI 1996/2194.

**Consequential revocation**

3. Regulation 3(3) of and Part III of Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(a) are revoked insofar as they apply to animal test certificates.

8th December 2003

*Ben Bradshaw*  
Parliamentary Under Secretary of State,  
Department for Environment, Food and Rural Affairs

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety



18th December 2003

*D. C. Gowdy*  
Permanent Secretary for the Department of Health,  
Social Services and Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development



18th December 2003

*Pat Toal*  
Permanent Secretary for the Department  
of Agriculture and Rural Development

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(a) SI 1971/972: the relevant amending instrument is SI 1972/1226.

## **EXPLANATORY NOTE**

*(This note does not form part of the Regulations)*

These Regulations revoke, with effect from 12th January 2004, the Animal Test Certificates Regulations 1996, which provide for the procedure by which application is made for an animal test certificate issued under the Medicines Act 1968 and which also set out statutory standard provisions incorporated into such certificates under the Medicines Act. Statutory standard provisions which were superseded by the 1996 Regulations are revoked insofar as they take effect upon the revocation of the 1996 Regulations.

In consequence, standard provisions will not be set out in statute, but will survive so far as incorporated in existing certificates (Interpretation Act 1978, section 16). It remains open to the licensing authority to issue new certificates with individual provisions (Medicines Act 1968, sections 20 and 36).

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