

**EXPLANATORY MEMORANDUM TO THE
MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCTS
(REVOCATION OF CONFIDENTIALITY PROVISION) REGULATIONS 2004**

2004 No. 3193

1 This explanatory memorandum has been prepared by the Veterinary Medicines Directorate (VMD), an Executive Agency of the Department for Environment, Food and Rural Affairs and is laid before the Parliament by Command of Her Majesty.

2. **Description**

The Marketing Authorisations for Veterinary Medicinal Products (Disclosure) (Revocation) Regulations 2004 will come into force on 1 January 2005 revoking regulation 14 of The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 ('the principal Regulations').

3. **Matters of special interest to the Joint Committee on Statutory Instruments.**

None

4. **Legislative Background**

Regulation 14 of the principal Regulations prohibits the disclosure by any person of any information with respect to any manufacturing process or trade secret obtained or furnished to him in pursuance of the principal Regulations. The VMD consulted on whether there would still be a need for regulation 14 when the Freedom of Information Act 2000 ('FOI') is fully implemented in January 2005. The majority of consultees supported the revocation of regulation 14 but only at the same time as the FOI came into force.

5. **Extent**

This instrument applies to the United Kingdom.

6. **European Convention on Human Rights**

Not applicable.

7. **Policy background**

7.1 In December 2002 the VMD carried out a joint consultation exercise with the Medical and Health Products Regulatory Agency on the possible repeal of section 118 of the Medicines Act 1968 (which applies to both human and veterinary medicines) and the revocation of regulation 14 of The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994. Both section 118 and regulation 14 prohibit the disclosure of information with respect to any manufacturing process or trade secret.

- 7.2 This consultation was carried out in preparation for the full implementation of the FOI on 1 January 2005. The majority of respondents to the consultation supported the repeal.
- 7.3 The Department for Constitutional Affairs (DCA), as part of a programme of repealing statutory bars to the release of information under powers contained in Section 75 of the Freedom of Information Act, is repealing section 118. However, DCA is focusing on the repeal of primary legislation and will not be able to deal with regulation 14 before 1 January 2005.
- 7.4 To avoid having conflicting legislation, which would maintain a criminal offence for officials releasing information, regulation 14 must be amended by 1 January 2005. It is government policy that unlawful breaches of confidence are to be civil torts only, irrespective of the status of the perpetrator. Thus rather than amend regulation 14 to disapply its scope from public officials, it should be revoked in its entirety.

8. **Impact**

It is not considered that the repeal of regulation 14 would have any financial or competitive effect on business, charities or voluntary bodies. A Regulatory Impact Assessment has not therefore been conducted.

9. **Contact**

John FitzGerald at the Veterinary Medicines Directorate can answer any queries regarding the instrument.

Tel: 01932 338303 or e-mail: j.fitzgerald@vmd.defra.gsi.gov.uk