2003 No. 1680

MEDICINES

CONSUMER PROTECTION

The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

Made - - - - -	*2nd July 2003*
Laid before Parliament	*9th July 2003*
Coming into force - -	*30th July 2003*

The Secretary of State, in exercise of the powers conferred by sections 11 and 27(2) of the Consumer Protection Act 1987(**a**), and of all other powers enabling him in that behalf, after consultation in accordance with section 11(5) of the Consumer Protection Act 1987 with organisations appearing to him to be representative of interests substantially affected by these Regulations and with such other persons considered by him appropriate, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 and shall come into force on 30th July 2003.

(2) In these Regulations—

"the 1968 Act" means the Medicines Act 1968(**b**);

"the 1987 Act" means the Consumer Protection Act 1987;

"the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**c**);

"the appropriate Minister" means—

(a) in Great Britain, the Secretary of State;

(b) in Northern Ireland, the Minister of Health, Social Services and Public Safety;

"CSM" means the Committee on Safety of Medicines established by the Medicines (Committee on Safety of Medicines) Order 1970(**d**);

"excluded medicine" means a herbal remedy or medicinal product to which the restrictions in—

(**a**) 1987 c. 43.
(**b**) 1968 c. 67.
(**c**) S.I. 1994/3144.
(**d**) S.I. 1970/1257.

(a) section 7 of the 1968 Act(**a**) (general provisions as to dealing with medicinal products) do not apply by virtue of section 10 of the 1968 Act(**b**) (exemptions for pharmacists); or

(b) regulation 3 of the 1994 Regulations (marketing authorizations for relevant medicinal products) do not apply by virtue of paragraph 3(1)(b) of Schedule 1 to the 1994 Regulations (exemptions for pharmacists from regulation 3);

"herbal remedy" has the meaning given in section 132(1) of the 1968 Act;

"import" means, in relation to an unlicensed product, import into the United Kingdom in the course of a business other than for the purposes of a clinical trial;

"market" means, in relation to an unlicensed product, a supply of the product, other than for the purposes of a clinical trial, which is also—

(a) the occasion on which the product is placed on the market in the United Kingdom;

(b) any occasion on which the product is distributed by way of wholesale dealing within the United Kingdom; or

(c) the exportation of the product out of the United Kingdom,

and for these purposes, "placed on the market" and "distributed by way of wholesale dealing" have the same meaning as in regulation 3 of the 1994 Regulations (marketing authorizations for relevant medicinal products);

"medicinal product" means—

(a) any medicinal product within the meaning given in section 130 of the 1968 Act(**c**) (meaning of "medicinal product" and related expressions); and

(b) any article or substance to which section 7 of the 1968 Act (general provisions as to dealing with medicinal products) has effect by virtue of an order under section 104 or 105 of the 1968 Act(**d**) (which relate to the application of the Act to certain articles and substances which are not medicinal products);

"supply", in relation to an unlicensed product, means—

(a) the supply of, or the offer or agreement to supply, the product; or

(b) the exposure or possession for supply of the product;

"unlicensed product" means a medicinal product for human use, other than an excluded medicine, in respect of which—

(a) no marketing authorization has been granted by—

(i) the licensing authority under the 1994 Regulations, or

(ii) the European Agency for the Evaluation of Medicinal Products under Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing the European Agency for the Evaluation of Medicinal Products(**e**); or

(b) no product licence has been granted by the licensing authority under section 7 of the 1968 Act (general provisions as to dealing with medicinal products);

"the TSE Guideline" means the "Note for guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" as published and updated by the European Commission in Volume 3 of its publication, "The Rules Governing Medicinal Products in the European Union", referred to in the Introduction to the Annex to Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**f**).

(3) In these Regulations, a reference—

(a) to a numbered regulation, is to the regulation of these Regulations bearing that number;

(**a**) Amended by S.I. 1977/1050, 1983/1724, 1992/604 and 1994/276. By virtue of regulation 9(2) of S.I. 1994/3144, section 7 of the 1968 Act does not apply to any medicinal product for human use which is a "relevant medicinal product" within the meaning given in regulation 1(2) of S.I. 1994/3144, amended by 2002/236; there are other amending instruments but none are relevant.

(**b**) Amended by S.I. 1971/1445, 1993/834 and 1994/2987.

(**c**) Amended by section 13(2) of, and paragraphs 3(7) to (10) of Schedule 1 to, and Schedule 2 to, the Animal Health and Welfare Act 1984 (c. 40), and by S.I. 1994/3199.

(**d**) *See* S.I. 1971/1200, amended by S.I.1994/787; S.I. 1971/1267, amended by S.I. 1994/3119; S.I.1973/367; S.I. 1975/533, amended by S.I. 1994/3119; S.I. 1976/968, amended by S.I. 1994/3119; S.I. 1978/1004; S.I. 1984/187; and S.I. 1985/1403.

(**e**) OJ No. L 214, 24.8.1993, p.1.

(**f**) OJ No. L 311, 28.11.2001, p.67.

(b) in a regulation, to a numbered paragraph is to the paragraph of that regulation bearing that number.

Compliance with the TSE Guideline

2. No person shall import or market an unlicensed product unless that product has been manufactured in accordance with the TSE Guideline.

Procedure for determinations of compliance with the TSE Guideline

3.—(1) The appropriate Minister may serve on any person who has imported or marketed, or who in his opinion may import or market, an unlicensed product a notice in writing requiring him, within a period of 21 days from the date on which the notice was served on him, to furnish the appropriate Minister with material demonstrating to the appropriate Minister that the product has been manufactured in accordance with the TSE Guideline.

(2) Where the appropriate Minister considers that, because of exceptional circumstances or the nature and complexity of the issues, additional time is needed to furnish material under paragraph (1), he may alter the period of 21 days referred to in that paragraph to a different period, and then that different period shall be the period within which the person on whom the notice is served is required to furnish the material.

(3) After the period allowed for furnishing material under paragraph (1), the appropriate Minister shall (whether or not he has been furnished with any material by the person on whom the notice was served), after further consideration of the matter—

(a) determine that, in his opinion, the product has been manufactured in accordance with the TSE Guideline, and shall notify the person on whom the notice was served under paragraph (1) of his determination; or

(b) provisionally determine that, in his opinion, the product has not been manufactured in accordance with the TSE Guideline, and shall, by a notice in writing (referred to in these Regulations as a "provisional determination notice")—

(i) inform the person on whom the notice was served under paragraph (1) of this provisional determination and his reasons for it, and

(ii) advise that person that if he disagrees with the provisional determination, he may request that the appropriate Minister review the provisional determination, provided that within 14 days of the date on which the provisional determination notice was served on him he makes such a request, and if that person wishes the review to include an oral hearing before the CSM (at which the appropriate Minister may also make representations to the CSM), he must also within those 14 days inform the appropriate Minister of his wish for such a hearing.

(4) Where the appropriate Minister has been informed pursuant to paragraph (3)(b)(ii) that a person wishes to make oral representations to the CSM, he shall, after consultation with that person ("the appellant"), set a date for the oral hearing and, subject to paragraph (5), that date shall be the date fixed for the oral hearing.

(5) Where the Chairman of the CSM considers that, because of exceptional circumstances or the nature and complexity of the issues, additional time is needed for preparation for the oral hearing, he may alter the date set for the hearing to a different date, and—

(a) that different date shall be the date fixed for the oral hearing; and

(b) the CSM shall inform the appellant and the appropriate Minister of the alteration and of the reasons for it.

(6) Where a person on whom a provisional determination notice is served fails within 14 days of the date on which the notice was served on him to request a review of the provisional determination, the appropriate Minister shall—

(a) after further consideration of the matter, determine whether or not, in his opinion, the product has been manufactured in accordance with the TSE Guideline; and

(b) by a notice in writing, inform that person of the determination and his reasons for it.

(7) Where a person on whom a provisional determination notice is served requests, within 14 days of the date on which the notice was served on him, a review of the provisional determination, but that review is not to include an oral hearing before the CSM, the appropriate Minister shall—

(a) specify a period within which the person must furnish the appropriate Minister with any additional material which that person wishes the appropriate Minister to consider as part of the review;

(b) once that period has expired (whether or not any further material has been submitted), after further consideration of the matter, determine whether or not, in his opinion, the product has been manufactured in accordance with the TSE Guideline;

(c) by a notice in writing, inform that person of the determination and his reasons for it.

(8) Where a person on whom a provisional determination notice is served requests, within 14 days of the date on which the notice was served on him, a review of the provisional determination and that review is to include an oral hearing before the CSM, the appropriate Minister shall—

(a) once that hearing has taken place (whether or not the appellant made any representations at the hearing), after further consideration of the matter, and in particular having considered the advice of the CSM arising out of the hearing, determine whether or not, in his opinion, the product has been manufactured in accordance with the TSE Guideline;

(b) by a notice in writing, inform that person of his determination and his reasons for it; and

(c) if the appropriate Minister makes a determination which is contrary to the advice of the CSM, give his reasons for disagreeing with the advice of the CSM.

(9) Where the appropriate Minister serves a notice under paragraph (1), he shall not issue a suspension notice under section 14 of the 1987 Act in respect of any unlicensed product to which the notice under paragraph (1) relates until he has determined in accordance with paragraph (6), (7) or (8) whether or not, in his opinion, the product has been manufactured in accordance with the TSE Guideline, unless he considers it necessary to issue such a suspension notice in the interests of safety.

Restriction notices

4.—(1) Where the appropriate Minister has determined in accordance with regulation 3(6), (7) or (8) that, in his opinion, an unlicensed product has not been manufactured in accordance with the TSE Guideline, he may serve a notice on any person—

(a) prohibiting him, from a date specified in the notice, from importing or supplying the product until the notice has been withdrawn by the appropriate Minister;

(b) requiring him, by a date specified in the notice, to inform persons of a specified class or description of the determination by the appropriate Minister that, in his opinion, the product has not been manufactured in accordance with the TSE Guideline;

(c) requiring him, by a date specified in the notice, to recover possession of any of the product that he has supplied to another person, or to persons of a particular class or description.

(2) Any person who is aggrieved by a decision to serve a notice under paragraph (1) may appeal within 7 days against that notice to a magistrates' court or, in Scotland, to the Sheriff, who may order that the notice be modified or withdrawn.

New evidence of compliance

5. Where the appropriate Minister has determined in accordance with regulation 3(6), (7) or (8) that, in his opinion, an unlicensed product has not been manufactured in accordance with the TSE Guideline, but the person on whom the notice was served satisfies the appropriate Minister that he has new evidence that may demonstrate that the product has been manufactured in accordance with the TSE Guideline, the appropriate Minister may—

(a) withdraw any notice he has issued under regulation 4;

(b) issue a further notice under regulation 3(1) on that person in respect of that product, notwithstanding the earlier determination.

Records of evidence of compliance

6.—(1) The designated record-keeper for an unlicensed product shall, if materials to which the TSE Guideline applies were used in the course of the manufacture of that product—

(a) establish records in English that demonstrate that the product has been manufactured in accordance with the TSE Guideline; and

(b) keep those records available for the appropriate Minister for a period of five years from the date on which he imports or markets the product, or for a period of one year from the expiry date for the product, whichever is the longer.

(2) For the purposes of paragraph (1)—

(a) a person is the designated record-keeper for an unlicensed product—

(i) if he is the person who imports the product, or

(ii) if the product has been manufactured or assembled in the United Kingdom, if he is the person who manufactured or assembled the product in the United Kingdom;

(b) if materials used in the course of the manufacture of an unlicensed product may be materials to which the TSE Guideline applies, they shall be deemed to be materials to which the TSE Guideline applies, unless the designated record-keeper for the unlicensed product is able to demonstrate that they are not materials to which the TSE Guideline applies.

Enforcement

7.—(1) In relation to unlicensed products, each weights and measures authority in Great Britain and each district council in Northern Ireland is relieved of the duty imposed by section 27(1) of the 1987 Act (enforcement) to enforce within their area these Regulations, and that duty is transferred—

(a) in Great Britain, to the Secretary of State;

(b) in Northern Ireland, to the Minister of Health, Social Services and Public Safety.

(2) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of regulation 2—

(a) a magistrates' court in England or Wales may try any information laid within 12 months from the time when the offence was committed;

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made within 12 months from the time when the offence was committed; and

(c) in Scotland, summary proceedings for the offence may be commenced at any time within 12 months from the time when the offence was committed.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
Department of Health

2nd July 2003

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations contain measures regulating the importation and marketing of unlicensed medicinal products for human use in order to minimise the risk of the transmission of Transmissible Spongiform Encephalopathies via those products.

Regulation 2 prohibits the importation or marketing of unlicensed medicinal products for human use, apart from some exempt medicinal products such as herbal remedies and clinical trial products, unless they have been manufactured in accordance with the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" as published and updated by the European Commission. There is a procedure for enabling the appropriate Minister (the Secretary of State or the Minister of Health, Social Services and Public Safety) to determine compliance with this Note for Guidance (regulation 3), and a notice procedure enabling the appropriate Minister to take action against non-compliant products (regulation 4). In cases where non-compliance has been determined, there is a procedure for revisiting the determination where the appropriate Minister is satisfied that there is new evidence of compliance (regulation 5).

If products are manufactured using materials to which the Note for Guidance applies, designated record-keepers for the products have to keep records of evidence of compliance for five years, or for one year after the expiry date of the product, whichever is the longer (regulation 6).

Local authorities are relieved of their responsibilities to enforce these Regulations, which are transferred in Great Britain to the Secretary of State, and in Northern Ireland to the Minister of Health, Social Services and Public Safety, and summary prosecutions for breach of regulation 2 may be commenced within twelve months (regulation 7).

These Regulations have been notified to the European Commission and to other Member States of the Community in accordance with Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services(**a**), as amended(**b**). A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**a**) OJ No. L 204, 21.7.1998, p.37.
(**b**) *See* Directive 98/48/EC (OJ No. L 217, 5.8.1998, p.18).

STATUTORY INSTRUMENTS

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