

# WORLD TRADE ORGANIZATION

G/TBT/N/GBR/4  
20 September 2002

(02-5033)

Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1.</b>	<b>Member to Agreement notifying:</b> <u>UNITED KINGDOM</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2.</b>	<b>Agency responsible:</b> Department of Health: Medicines Control Agency Market Towers, No.1 Nine Elms Lane, London, SW8 5NQ <b>Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> UK TBT Enquiry Point, Department of Trade and Industry:  European communities TBT Enquiry Point ec-tbt@cec.eu.int
<b>3.</b>	<b>Notified under Article 2.9.2 [ X ], 2.10.1 [   ], 5.6.2 [ X ], 5.7.1 [   ], other:</b>
<b>4.</b>	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Any medicinal products for human use which are supplied under UK law other than in accordance with a marketing authorization under either Directive 2001/83/EC or the UK national scheme for regulating medicines not covered by the Community scheme, the Medicines Act 1968.  The two main categories of unlicensed medicines are:  (a) medicines (commonly know as "specials") which are exempt from licensing because they are supplied in response to the unsolicited order of a doctor or dentist to meet the special needs of an individual patient on his direct personal responsibility;  (b) medicines (excluding herbal remedies) mixed, assembled and supplied by someone who is not a doctor or dentist, (known as a "non-orthodox practitioner"), to a patient who has consulted him about his health.  In addition, any substance which, although not requiring a marketing authorization is classified as a "medicinal product" with the united Kingdom, as is regulated accordingly.
<b>5.</b>	<b>Title, number of pages and language(s) of the notified document:</b>  Draft Regulations, The Unlicensed ;Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations S.I. 2002  Number of pages: 11  Language: English

6.	<b>Description of content:</b> The proposed draft Regulations will prohibit the importation or marketing of unlicensed medicinal products for human use, 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 are exemptions for herbal remedies, products for clinical trials, and products produced by or under the supervision of a pharmacist. There is procedure for determining compliance with the Note for Guidance, involving adjudication by an expert committee, and designated record keepers in the United Kingdom have to keep records of compliance.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> There is convincing evidence to show that a variant form of Creutzfeld-Jakob Disease, which is responsible for a number of deaths in the United Kingdom, has been caused by an Animal Spongiform Encephalopathy agent, BSE. All licensed medicines in the UK are now required to comply with this Note for Guidance. UK Ministers now want to protect patients from the same risk arising from unlicensed medicines. As the Commission's TSE Guideline states: "... due prudence continues to be warranted if biological materials from species affect by ... [Transmissible Spongiform Encephalopathy] diseases other than by experimental challenge especially bovine species, are used for the manufacture of medicinal products."
8.	<b>Relevant documents:</b>  Draft Partial Regulatory Impact Assessment document.  Draft Regulations, The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations S.I. 2002 ...  Note or Guidance on Minimising the Risk of Transmitting animal Spongiform Encephalopathy Agents via Human Medicinal Products
9.	<b>Proposed date of adoption:</b> <b>Proposed date of entry into force:</b> } The period of consultation in the U.K. ends on 20 November 2002. If after the comment period, the Secretary of State for Health decides to proceed with the proposal, the likely adoption date is some point in April 2003, with a likely entry into force date at some point in May 2003.
10.	<b>Final date for comments:</b> 9 December 2002
11.	<b>Texts available from: National enquiry point [ X ] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b>  UK TBT Enquiry Point, Department of Trade and Industry, Kingsgate House, Bay 310, 66-74 Victoria Street, London, SW1E 6SW. Email: andy.weller@dti.gov.uk Tel: +44 207 215 4548, Fax: +44 207 215 4249