

NOTIFICATION

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

1. Member to Agreement notifying: <u>MALAYSIA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: National Pharmaceutical Control Bureau Ministry of Health Jalan Universiti, Peti surat 319 46730 Petaling Jaya Selangor Fax: (+603) 79562924 Phone: (+603) 79573611 E-mail: eishah@bpfk.gov.my Web site: www.bpfk.gov.my 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:
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Pharmaceutical and Healthcare Products (ICS: 11.120.10)
5. Title, number of pages and language(s) of the notified document: Amendment to the "Drug Registration Guidance Document", National Pharmaceutical Control Bureau, Ministry of Health Malaysia, April 2004 (33 pages, in English and Malay). Appendix 1 is amended to include provision for product authentication by means of a security device.
6. Description of content: The amendment prescribes the mandatory requirement for the use of a hologram security device on medicinal products sold in Malaysia. It is applicable to all pharmaceutical and traditional products, locally manufactured or imported.
7. Objective and rationale, including the nature of urgent problems where applicable: <ul style="list-style-type: none">- Protection of health and safety- Prevention of deceptive practices

8. Relevant documents: <ul style="list-style-type: none">(i) Drug Registration Guidance Document, National Pharmaceutical Control Bureau, Ministry of Health Malaysia, April 2004(ii) Sales of Drugs Act (Act 368) 1952 (Revised – 1989)(iii) Control of Drugs and Cosmetics Regulations 1984(iv) Directive on the Use of the Hologram Security Devise (Meditag™)
9. Proposed date of adoption: 5 August 2004 Proposed date of entry into force: 1 May 2005
10. Final date for comments: 60 days from date of notification
11. 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: National Pharmaceutical Control Bureau Ministry of Health Jalan Universiti, Peti Surat 319 46730 Petaling Jaya Selangor Fax: 603 79562924 Phone: 603 79573611 E-mail: eishah@bpfk.gov.my Web site: www.bpfk.gov.my