National Pharmaceutical Control Bureau (NPCB)
Ministry of Health
MALAYSIA

Berita Ubat-ubatan
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

REGISTRATION OF TRADITIONAL MEDICINES IN MALAYSIA

Berita Ubat-ubatan April 1999

The registration of traditional medicines was implemented in 1992. Since then, over a period of seven years, the National Pharmaceutical Control Bureau has received 17,421 applications, of which 14,186 are existing traditional products and 3,235 are new traditional products. 70% of the applications are for Chinese traditional medicines, 12% for Malay traditional medicines, 15% for Western traditional medicines while the remaining 3% are for Ayuverdic, Unani, Siddha and Homeopathic products.

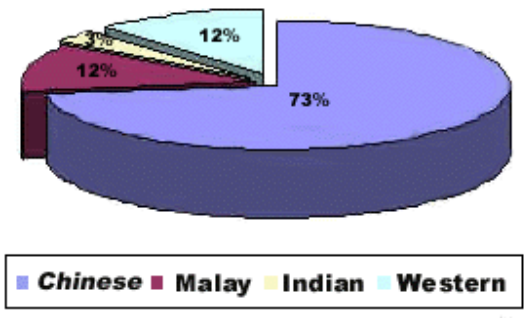
Imported products represent 46% while locally manufactured products constitute 54% of the Clove applications received.

Applications For Registration of Traditional Medecines88

Year	1992	1993	1994	1995	1996	1997	1998	Total
No. of applications received	3973	3709	4080	288	415	668	938	17421
No. of applications approved	-	5	52	282	1513	2502	3842	8196
No. of applications rejected	-	-	410	843	1317	1345	3435	7350
No. of applications pending approval	-	-	-	-	-	-	-	1875

Since 1993, the DCA has approved 8,196 applications for registration and rejected 7,350 applications.
The table above shows the number o f applications received, the number of applications approved and the number of applications rejected by the DCA from 1992 to 1998. The number of applications pending approval at the beginning of this year is 1,875.

Traditional Products Registered



The largest group of traditional medicines approved by the DCA is the Chines traditional medicines which constitute 73% of the traditional products registered.The chart indicates the proportion of Chinese, Malay, Indian and Western traditional products registered with the DCA.

Registration of Traditional Medicines (existing products)

All local traditional medicine manufacturers must comply with Good Manufacturing Practice (GMP) requirements by 31st December 1998 and the importers of traditional medicines must possess valid Import Licenses by 1st January 1999. With respect to that, the Drug Control Authority at its 101st meeting has made the following decisions:

For locally manufactured products with registration validity period up to 31st December 1998

- Manufacturers who had complied with the GMP requirements:

  Their product registration validity will be extended to 5 years from the date of registration.

- Manufacturers whose premises are undergoing renovation/construction:

  Their product registration will be extended only if they comply with GMP requirements before 30th June 1999. If they fail to meet the dateline, their product registration will be cancelled by the DCA.

- Manufacturers whose premises fail to comply with the GMP requirements:

  Registration of their products will be cancelled. However if the product registration holder can appoint a licensed contract manufacturer to manufacture their products and submit the application to change manufacturer before 31st March 1999, they can have their product registration validity extended to 5 years from the date of registration.

Imported products

Importers of traditional medicines must have valid Import Licenses by 1st January 1999. For "existing products", which are still under evaluation, the applicant can obtain a permit to import them from the Secretary of the Drug Control Authority.