National Pharmaceutical Control Bureau (NPCB)
Ministry of Health
MALAYSIA

Berita Ubat-ubatan
NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

# REGULATORY CONTROL BEYOND 2000

**Berita Ubat-ubatan August 2000**

The promulgation of the Control of Drugs and Cosmetics Regulations in June 1984 marked the dawn of the regulatory era in Malaysia. This laid the groundwork necessary towards moulding a systematic pharmaceutical regulatory system in Malaysia. In January 1985, the Drug Control Authority ( DCA ) was established with a mission of ensuring quality, safety and efficacy of pharmaceutical products prior to marketing.

The registration exercise was successfully implemented in phases, commencing with Phase 1 for prescription drugs in November 1985, followed by Phase 2 for OTC products in August 1988 and Phase 3 for traditional medicines in January 1992. Although Phase 4 for cosmetics has not been announced yet, hair-dyes containing scheduled poisons and tooth-whiteners are currently being regulated.

As of 31st December 1999, a total of 43,299 applications had been received and the total number of products registered stands at 23,935.

**Registration of Cosmetics**

Increasing concerns about safety and health-related problems associated with cosmetics have made it necessary for cosmetic ingredients to be evaluated scientifically. As cosmetics may be used extensively over a large portion of the body, there is a need to control the ingredients used and to monitor their potential hazards.

*(Please refer to Berita Ubat-ubatan September 1999 for a detailed write-up on Cosmetic Registration in Malaysia)*

As mentioned earlier, the effective date for the registration of cosmetics is yet to be decided.

**Registration of Veterinary Medicines**

The Ministry of Health has been urged to implement registration of veterinary pharmaceuticals to ensure quality and safety. The relevant amendment to include control of veterinary medicines in the current Act and Regulations was passed by Parliament on 13th July 2000. The DCA has been entrusted to undertake this expanded role with appointment of new member(s) representing the veterinary services.

Although the framework and mechanism for registration of veterinary medicines would most likely follow procedures currently adopted for drugs intended for humans, existing guidelines must be amended to include veterinary medicines, where appropriate. A Technical Working Group (TWG) for veterinary medicines has been formed to steer the project through.

There is a need to consider contributions from experts in the various fields to assist in the implementation of policies. Since Malaysia now adopts the EU GMP Guidelines for Medicinal Products for Human and Veterinary Use (1997), implementation of veterinary GMP in Malaysia will have to be consistent with these requirements.

It may be still early to indicate when registration of veterinary medicines will be implemented. Nevertheless, prior to implementation, approaches adopted by other regulatory authorities world wide are being studied.

**Regulatory Control of Medical Devices**

The implementation of registration of medical devices in Malaysia was earlier proposed under the 7th Malaysia Plan when efforts were initiated in 1996 to seek approval from the Planning and Development Committee, Ministry of Health Malaysia. A special committee involving government and industry representatives has been established to draft the proposed Act and Regulations. The 2nd Draft of the Medical Device Act and Regulations are currently being reviewed.

While the regulatory authority has an important role to play, the implementation of regulatory control for medical devices needs co-operation from the industry, hospitals, engineers, health technology organizations, universities, research institutions, healthcare delivery and consumer organizations, and collaboration with the Medical Device Global Harmonization Task Force ( GHTF ).

The GHTF, whose goals include development of congruent requirements, defining common regulatory approaches, reducing trade barriers, facilitating market availability, establishing partnerships, leverage of international resources and fulfilment of shared public health mandate, is a useful platform for interaction and acquiring information and guidance documents.

Adopting a voluntary compliance approach, which will later evolve towards regulatory control with particular emphasis on quality assurance and post-marketing surveillance, may be a possible start for the implementation of medical device registration in Malaysia.

**Regulatory Control of Active Pharmaceutical Ingredients ( API )**

In tandem with developments of the International Conference on Harmonization

(ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) towards multi-national efforts for universal harmonization of a current GMP Guide for Active Pharmaceutical Ingredients ( API ), Malaysia should keep abreast of this new regulatory requirement. The draft API Guide was also circulated to Malaysia in September 1997 for comments. The proposed draft is basically similar to that for finished pharmaceutical products with additional requirement for APIs for Clinical Trials.

The need for regulatory control of APIs has been strongly proposed by WHO as an effort towards combating counterfeit drugs. As regards to GMP for pharmaceutical products, which emphasizes the importance of quality raw materials, such need for GMP for APIs is indeed justified.

Currently only one local manufacturer is involved in the synthesis of raw materials, which includes diclofenac sodium, nifedipine, atenolol, salbutamol, betamethasone, terbutaline sulphate and trimethoprim for local and export markets.

From the legislative perspective, the Poisons Act 1952 ( revised 1989 ) currently regulates the importation, possession, manufacture, compounding, storage, transport, sale and use of scheduled poisons, while the Control of Drugs and Cosmetics Regulations 1984 regulates pharmaceutical products. Thus, the relevant Act and Regulations may need to be reviewed to allow for the registration and licensing of APIs in future.