Monday, 17th January, 2000

Mr. Anthony Chan
Chief Pharmacist
Department of Health
18/F Wu Chung House
213 Queen's Road East
Wanchai
Hong Kong

Dear Anthony,

Product Registration

A few of our members have expressed their concern over the delay of their new product registration. A list of such products is attached.

We knew that the Pharmacy and Poisons Board may have approved such products after the 8th October 1999 meeting, but due to delay elsewhere with the administration the final procedure with the Legco is still pending.

The Association wishes to thank you for letting our members know their new registration number to help them reducing time to prepare the import package.

Please keep us informed of results of the final step.

Thank you.

Yours sincerely,

Robert Siu
Executive Director

Company	Chemical Entity	Date of Complete Registration File Submission	Number of month after file submission
1. Boehringer Ingelheim	Telmisartan	Final May	9
2. Glaxo Wellcome	Zanamivir	Final May	8
3. Knoll	Srbutramine	Final 14th May	10
4. M.S.D	Rofecoxib	22nd June 1999	6
	Efarirenz	Final July	12
5. Sanofi-Synthelabo	Miglitol	final 20th April 1999	8
6. SciClone	ZADAXIN® INJECTION	June 1998	18

Registration of New Chemical Entities

Members of the Regulatory Affairs Committee Annette Chiu, Alfred Tsang, Kim Lee and myself visited Mr. Fletch Chan of the Health and Welfare Bureau. Mr. Chan is the assistant to Mr. Gregory Leung, Deputy Director of Health and Welfare Bureau.

The Registration Approval Document after reviewed and approved by the Pharmacy & Poisons Board will be directed to the Health and Welfare Bureau (To Mr. Fletch Chan). This time after the 8th October 1999 meeting, it arrived at the Health and Welfare Bureau at the end of October (3 weeks). During this 3 weeks, we were told by Mr. Fletch Chan that the Department of Health was preparing the "Drafting instruction".

In early November, the Health and Welfare Bureau direct this "instruction" to the Legal Department for law drafting. At the end of November (another 3 to 4 weeks) the Legal Department return their first drafting to the Health and Welfare Bureau to confirm accuracy of the wordings. This was return to the Legal Department in 2 to 3 days time for them to prepare the FINAL VERSION of the "AMENDMENT OF LAW". Mr. Fletch Chan told us this will take another 2 weeks before it is forwarded to the Secretary for Health and Welfare Bureau for his signature. The Secretary will then prepare a speech for the Legislative Council meeting, at the same time the Health and Welfare Bureau will request a slot time with the secretary of the Legislative Council to arrange the "Amendment" to be presented to the Legco member. It will normally takes 20 working days between the application of a "SLOT TIME" to the actual presentation at Legco (normally on a Wednesday). Normally on the same Friday after Legco procedure the "Amendment" will be gazetted and in the following week the Department of Health will inform the member company the effective approval date of the new chemical entity. Most of us are not familiar with the dealing after passing the Pharmacy and Poisons Board. Now at least we know who are the people that is responsible after it passed Mr. Anthony Chan, and also the normal time required before our new chemical entity can be approved.

Illustration of the current batch of New Chemical Entity under review

- APPROVAL BY PHARMACY & POISONS BOARD — OCT. – 8

- DEPARTMENT OF HEALTH TO PREPARE THE DRAFTING INSTRUCTIONS — END – OCT.
  (3 WEEKS)

- HEALTH AND WELFARE BUREAU TO FORWARD TO LEGAL DEPARTMENT FOR FIRST DRAFTING — EARLY NOV.
  (1 WEEK)

- LEGAL DEPARTMENT RETURN FIRST DRAFTING TO HEALTH & WELFARE BUREAU — END NOV.
  (3 WEEKS)

- HEALTH & WELFARE BUREAU CHECKING ON ACCURACY OF WORDINGS — EARLY DEC.
  (2-3 DAYS)

- RETURN DRAFTING TO LEGAL DEPARTMENT TO PREPARE FINAL VERSION — MID DEC.
  (2 WEEKS)

- SECRETARY FOR HEALTH AND WELFARE TO SIGN ON DRAFT AMENDMENT
  (2-3 DAYS)

- LEGISLATIVE COUNCIL MEETING
  (20 WORKING DAYS)
  4 WEEKS

- GAZETTE → HWB TO SET EFFECTIVE DAY
  (2 DAYS)
  [NCE → 1 WEEK
  OLD PRODUCT
  → GRACE PERIOD]
  ↓ (ONE WEEK)
  GAZETTE EFFECTIVE DAY

- DEPARTMENT OF HEALTH TO INFORM APPLICANT TO COLLECT CERTIFICATE

TOTAL TIME NEEDED AFTER APPROVAL BY PHARMACY & POISONS BOARD — 15 WEEKS

* We were also informed that the Health & Welfare Bureau is trying to push the amendment to 29(i) of the Pharmacy & Poisons Ordinance with the Legislative Council in January 2000.

Record by ROBERT SIU