

Kogenate meeting - New Zealand - February 1 & 2, 1997

The Kogenate meeting was arranged by Jill Porter who had done an excellent job of preparing. The meeting was conducted over a two day period - February 1 and 2.

On the first day of the meeting, Christine Lee of Royal Free Hospital in London acted as the chairperson. Speakers were:

1. Dr. Martin Inwood of Canada - Canadian perspective with Kogenate in treating PUPS.
2. Dr. Mike Kowollenko of Bayer Berkeley - CJD and its implication on plasma products.
3. Dr. Christine Lee of the UK - UK cost situation in the treatment of hemophilia.
4. Dr. Jan Arstermark of Sweden - Swedish perspective in prophylaxis treatment of hemophilia.
5. Dr. Bob Kuhn of Bayer Berkeley - KG2 and future of recombinant F-VIII.

The afternoon of the first day was used for outdoor activities, where the guests were invited to take part in various activities, such as white-water rafting, 4-wheel drive into mountains, etc.

The second day of the meeting was chaired by Drs. Paul Ockelford of New Zealand and Kevin Rickard of Australia. Speakers presented their respective local situation with the hemophilia care.

Taiwan - February 4 - 5, 1997

1. Meeting with Prof. Shen - National Taiwan University Hospital
 - a) Patients records at the end of the 26th week were reviewed by Ralph and Sandy. There were some inconsistencies which required clarifications.
 - b) To clarify these inconsistencies, a meeting was held with Prof. Shen, and to review the raw patient records.
 - c) Since it was not possible to resolve all questions in this meeting, inconsistencies were explained and requested Prof. Shen to review the patient record and correct any errors in recording.
 - d) details of inconsistencies were written in a letter to Prof. Shen so as to make follow up easier.
 - e) Tony from TST will meet with Prof. Shen's assistance to review all the data to resolve inconsistencies during the following week.
2. Meeting with Department of Health - On HIV Situation

I was invited by Dr. Yeh of DOH on to discuss the HIV issue. A meeting was held on February 4 with Dr. Yeh.

At the start of the meeting, Dr. Yeh wanted to know if Bayer had a policy to deal with HIV infection of hemophilia patients who have been infected with F-VIII concentrate.

It was explained that Bayer did not have any formal policy. Since this is a legal issue, I was not the proper person to discuss this issue.

The following is a brief summary of our discussion.

- a. Cutter's Koate was the only concentrate used in Taiwan during the early '80's. I explained that HIV infections may have been caused by other treatments the patients may have received, such as cryoprecipitate and other blood components.
- b. I was requested to explain the litigation and settlement relative to the USA and Japan. It was emphasized that in all court cases where Bayer (Cutter/Miles) was involved with HIV litigation, the court had ruled in favor of Bayer. The settlements were offered to prevent prolonged litigation process which is very time consuming and expensive proposition for the industry. The companies involved agreed to settle the matter, with the understanding that no further litigation will be brought forth by the same people.
- c. It was agreed that nobody is to be blamed for the transmission of the virus in Taiwan, since all parties (i.e. Cutter and our distributor, the DOH, and the treaters) took appropriate actions to replace non-heat treated F-VIII concentrate when the heat treated product became available.
- d. The DOH is not saying that Bayer should compensate the patients because of its negligence, but wants to know if Bayer will be willing to consider doing something to show its concerns for the patients and its families for the misfortune. It was agreed that this is not a legal but a humanitarian issue.
- e. It was mentioned that I cannot speak on behalf of the company in issues such as this, and it is necessary for me to contact our legal department. It was mentioned that whatever we may say or do in this matter, we are not to be seen as admitting our negligence or guilt.
- f. If and when Bayer is to consider doing something for the patients, it would be difficult to determine what is considered appropriate, since we do not know the local situation or the culture in which these matter is to be considered. Therefore, it was suggested, it would be better, if a "committee" consisting of representatives from Bayer, DOH, hemophilia treaters and social workers be formed and discuss and decide what course of action may be appropriate.
- g. It was emphasized that in any situation, we do not want Bayer name be involved in a publicity or be mentioned in the news media. This was agreed.
- h. Whatever, action decided by the committee, the action is to be taken by the "committee" and not by Bayer. If any monetary compensation is

to be made, there should be a "fund" established, into which all contributions are to be made, and distribution of the money is to be made in the name of the fund, not in individual participants' names. This is to keep the names of parties anonymous.

- i. A concern was raised that any "compensation" agreed and offered by the committee may not satisfy the entire patient and family group. Dr. Yeh agreed that it may not, but assured us that the government will take every step to avoid any "escalation" of the compensation.
- j. It was agreed that I will contact our legal department to see if they would consider such an arrangement. Feed back will be made through our distributor (Tian Shing Trading).

My personal thought on this matter:

Bayer should show a willingness to work with the government on this matter for the following reasons:

- a. By so doing, we will be seen as a "responsible citizen" who is concerned about the welfare of the public. Conversely, if we do not cooperate, we will be seen by the government as a company not concerned and only interested in making profit in Taiwan.
- b. This will be a "team" effort, where a committee will be working together to come up with a solution to this difficult issue. This may be used to strengthen our relationship with the government and the hemophilia treaters.
- c. Assuming that the final solution will involve some monetary compensation, the payment will be done in such a way to avoid bringing Bayer name into the picture.

3. Meeting with Bayer Taiwan - February 5, 1997

- a. I met with Christian Velmer to discuss the issues relative to the transfer of BP business to Bayer Taiwan.
- b. It was confirmed that we are still planning to approach TST by the end of February to announce our intention to transfer the business to Bayer Taiwan.
- c. It was agreed that it is necessary for us to develop a "strategy" with which we approach Tian Shing.
- d. It was agreed that it is important for both Chris Smith and Christian Velmer to be present at the meeting with TST, to give an assurance that the transfer will be made in smooth and cooperative manner.
- e. Based on Tian Shing's gross profit analysed by Bayer Taiwan (which is estimated to be about 31% of the sales), it was agreed that we can offer 25% commission to TST. It is necessary for us to confirm the figures used by Bayer Taiwan in the analysis.
- f. I provided the Tian Shing's sales into main Medical Centers. This information will be important to confirm that most of BP business

concerns those medical centers in which Bayer Taiwan is already doing Pharma business.

- g. I promised to provide Tian Shing's organizational structure with number of sales reps involved in the BP business. This is to be used to estimate the cost of running the sales and other associated activities in Tian Shing.
- h. It was tentatively agreed that we travel to Taiwan to meet with Bayer Taiwan on February 26 and to meet with Tian Shing on the 27th.
- i. I briefed Christian regarding the latest issues on the sealing test, and HIV issues. REDACTED

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4. The DOH is not saying that Cutter