Dr Tsang

From J Sloggem
Date 26 September 1996
Copies Dr Rotblat O/R
File PL/3070/0007/C

HYATE:C MULTISTATE APPLICATION No 408 PL/3070/0007/C.

SPEYWOOD PHARMACEUTICALS LTD

1. Dr Rotblat asked me to pick up this application. I indicated that the submission we had in house was in draft. Dr Rotblat said that I should not assess a draft submission, and that I should confirm the status of the data with the Company.

2. Mrs Stronell told me that this product appeared on the CPMP agenda for October, and asked whether the Company had sent in data, and whether it had been assessed. It appeared that the Company had not sent out any data to other concerned member states, since Speywood considered that the responses submitted to the UK were in draft. Mrs Stronell advised the UK CPMP representatives accordingly.

3. I spoke to Mrs Burt of Speywood on 12 and 16 September, and confirmed the responses were not at that stage formal responses, and that there was no summary of data, which could be used as a basis of a document to be used as a basis of a report, for use at the Biotechnology Working Party. No data had been circulated to other concerned member states.

4. I asked Speywood to produce a summary of answers to questions raised by other member states, to facilitate the production of a report for Biotechnology WP/CPMP; with supporting annotated flow diagram, and a summary of changes made in production, QC/specifications an a result of the issues raised by the concerned member states.

5. The Company also wanted guidance about what the EMEA wanted about the handling of this multi-state application. Dr L Heng advised that an up to-date SPC was essential, and that to be considered as a multistate application it would need to be considered at either the November or December 1996 CPMP. Thereafter, she advised it would be considered as either a mutual recognition or list A product. With the list A status being the more likely status assigned.

6. I relayed this information to Mrs Burt. The Company said it would let MCA know what the timing would be that they would aim for, to make the formal submission of data for the Hyate:C response. When I spoke to Mrs Burt on the 16 September, she indicated that the Company were preoccupied with answering questions raised by the French authorities on the Company's *national* application in France. They would however endeavour to let MCA have the requested summary questions and answers by Monday 23 September.

7. On my return to the office on 24 September 1996, Dr Rotblat said Speywood had not formally submitted a formal response [see fax of 20 September], and that I should deal with the Centeon HSA applications instead.

8. The 20 September 1996 fax commits the Company to submitting a formal response by the EMEA 4 November deadline. Advice was requested by Speywood about the number of copies of data other concerned member states require, coupled with the suggested summary document.I suggested direct contact with the authorities concerned would be the best approach.

9. Mrs Burt telephoned me to-day [25/9/96]. I confirmed that it was my intention to use the summary document as the basis of the report put to Biotechnology WP/CPMP. However again the Company re-iterated a request for feedback on their draft responses. I replied that I had been told that we were not to deal with draft responses. Mrs Burt said that, in that case and given the short time scale, the responses submitted to the UK should be considered formal final responses. However the Company were concerned about the format of the summary document especially since I wished to use it as the basis of the report to Committees They were keen to have a meeting to discuss its content and format. I said I would discuss their request with Dr Tsang.

10. Mrs Burt also told me that Prof. Trouvain from France had suggested to the Company, at a meeting last week, that all concerned member states should meet to discuss the issues raised in the various assessments made.

11. I would suggest that in the first instance, the UK meets Speywood to discuss the format and content of the summary document, I think it will allow progress to be made. The product is on batch release, can in view of the proposed changes to QC/specifications, I think it would be helpful if Dr T Barrowcliffe were present. The Company would like a meeting as soon as is practicable.

12. Please may we discuss.

J. Sloggem,
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