Interoffice correspondence

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to:	C. Chard	date:	April 25, 1983
from:	A. Cameron	copies:	J. O'Sullivan J. Van Calster - TIS E. Platteau - TIS
subject:	MEETING AT DHSS WITH DRS. FOWLER AND PURVES		

C. Chard and A. Cameron met Dr. L. K. Fowler and Dr. J. Purves of the Medicines Division of the DHSS to discuss issues relating to the Hyland Therapeutic Ranges and several other Regulatory areas.

1. Plasma Protein Fraction/Buminate

Both the DHSS and NIBSC have expressed concern about the dual labelling of Albumin Solutions 5% as PPF and Buminate. In view of this we proposed that we would submit a new product licence for a Plasma Protein Fraction that would more loosely resemble the current BP or proposed Ph. Eur. specifications for such a product.

Dr. Purves stated that this would be the best approach and that an abridged licence application would be adequate. This application would not go to Committee stage as the product is similar to one currently produced. Also cross reference to other files could be used (as long as page and volume numbers are quoted). If no stability data is available the application will still be considered as long as positive statements on intention are made and that we inform the DHSS should any parameters go out of limits.

We will have to apply to remove the variation previously granted to label PPF and make a statement as follows:-

"We propose to discontinue marketing of PPF ____ months after granting of a new licence".

Dr. Fowler stated that we should submit a file to meet BP requirements at present and then vary this to meet Ph. Eur. when these proposals are eventually satisfied.

2. Hemofil-T

Drs. Fowler and Purves had previously received details of this study and stated that they could not really comment on this product and we should submit the file and wait for the response. The final Product Licence Application would have to be seen at Committee level and, although product costs should not come into the discussion, the overall cost/benefit would be examined.

One issue that would have to be included in the final submission would be a quantification of hepatitis risk reduction on heating.

3. Autoplex Trial

An update on the progress of the trial to date was given. Dr. Fowler appreciated the difficulty in obtaining sufficient bleed numbers and stated that, from his own experiences with clinical trials, only intensive follow up of all praticipating clinicians was likely to produce results.

4. Heparin

C. Chard mentioned that this file will be resubmitted but for only 2 strengths. Dr. Purves mentioned that he required adequate stability data on this product because of the heat sterilisation step (rather than the more normal filter sterilisation).

5. Labelling of Fenwal Optimal Additive System

Dr. Wagstaff has mentioned the Transfusion Centre Directors' concern at the labelling of the packs in the Optimal Additive System after collection and separation of blood. The primary pack (labelled as CPD) finally contains red cells suspended in SAG-M solution. Dr. Fowler stated that our responsibilities lay in correctly labelling the packs initially and, after that, the responsibility for relabelling after separation procedures lay with the Blood Transfusion Centre. He suggested that we could perhaps supply overstickers but could see no legal obligation to do this or to change current labelling procedures.

6. Intravenous Immunoglobulin Preparation

The problems of organising a trial to demonstrate clinical efficacy were discussed. Dr. Fowler suggested that we go for a product licence with a very limited lable claim - e.g. for raising immunoglobulin levels in agamma or hypogamma-globulinaemic patients. This should be relatively easy to demonstrate in a small trial and we could then use variations to widen the label claim as evidence was produced. We would then have a marketable product available and we could run trials in parallel (under CTX cover).

Overall Conclusions

The meeting proved very useful and Drs. Fowler and Purves made many constructive suggestions as to future Regulatory approaches for new products.

One point that was raised by Dr. Fowler was the increasing use of "Release on Prescription Only" as a means of marketing products without a Product Licence. This issue has been raised at a very high level (Secretary of State for Health) and has occurred because of large figures appearing on Health Authority budgets for products which are not licenced. The DHSS considers that the "Prescription Only" system of release is being misused by several companies - as an alternative to obtaining a Product Licence. There is a considerable likelihood of the system being "tightened-up" to prevent continued abuse by large companies.

Regards,

GRO-C

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C. Cameron