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NOTES OF A MEETING TO DISCUSS VIRUS INACTIVATION IN S8

DATE: 16th October 1990

PRESENT: R.J. Perry
H. Hart
B. Cuthbertson

This meeting was convened to discuss the recent data which indicates that the degree of virus inactivation in the current formulation of S8 is less than that in current Z8. In addition, the degree of vaccinia kill in S8 is less than the U.K. minimum standard when only the heating step is considered. However, adding virus kill over freeze drying and heating, a somewhat different picture emerges. On the basis of available data the following recommendations were made:

1. The next batch of S8 should go ahead as planned.

2. The clinical trial should go ahead as planned.

3. Further virus inactivation experiments should be carried out urgently on the existing formulation.

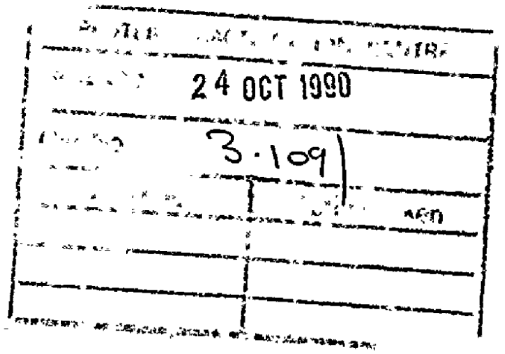
4. Alternative formulations should be explored by R&D with the objective of increasing virus kill but retaining solubility characteristics.

5. No S8 should be released for routine clinical use until the extra data defined above has been thoroughly evaluated and it can be concluded that S8 is equally as safe as Z8.

Bruce is this what you mean?

GRO-C

B. Cuthbertson
18th October 1990.



→ Bob Ram

Yes

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