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rjp.imm 2.167

11 January 1984

Dr D B L McClelland  
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Dear Brian

**FACTOR VIII : BATCH SIZE AND EXPIRY DATING**

With reference to your letter of 5 January I can offer the following comments:

1. Anticipated batch size for F VIII will almost certainly not rise above 4-5000 donations within the next year or two though it would be our wish to extend this ultimately as a means of achieving more efficient use of plant, equipment and staff resources. However, we are at present constrained by an 8 hour working day which effectively limits the plasma throughput to approximately 1 000 - 2 000 litres. It is reasonable to assume, that for the purposes of your explorations that smaller batch sizes will become very much in the minority - though possibly never quite disappear.
2. The current shelf-life of F VIII is, as you know, two years from the date of manufacture. It is not our wish to extend this and indeed we have little data on which it would be justified to do so. However, a recent assessment of the SNBTS stocks of F VIII suggests that for purposes of reducing the possibility of product outdating, it may be necessary, as one option, to extend the shelf-life to three years. We are in the process of generating data on product stored for three years but this is embryonic. Preliminary data suggests that a three year shelf-life may not provide a sufficient margin for safety. I believe that the question of F VIII shelf life may profitably be discussed at the forthcoming Co-ordinating Group Meeting (F VIII - Supply and Demand January 17th).

I understand your desire to dedicate batches of F VIII to individual patients but wonder if this is the same as dedicating individual patients to specific batches of F VIII since this is probably more practicable. Presumably if one were to dedicate/

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dedicate batches to patients there would inevitably be a substantial residue of "bin ends" which could outdate.

I hope these comments are of some help - please contact me if you require more information.

With kind regards.

Yours sincerely

R J PERRY  
Director (Acting)