

Ms Kirk

From: M A Harris HSI  
Date: 19 October 1988

c.c. Mrs Goldhill  
Miss Harper  
Mr Hart  
Mr Heppell  
Dr Harris  
Mr Cashman  
Dr Pickles  
Dr Moore

*McInnes*

*or 14K*

Self Sufficiency in Factor VIII for Haemophiliacs

Your minute of 17 October refers.

SUMMARY

The new BPL can be seen as a qualified success.

The good news:- It is already processing at planned capacity; it was timely in introducing a new heat treated factor VIII, acknowledged as among the best in the world; and is achieving yields well in excess of any commercial manufacturers.

*max. thr. capacity planned*

*for VIII only*

*can we see some share?*

The bad news:- The yields being achieved are however less than expected, and we will not be able to fully meet forecast demand for factor VIII from haemophiliacs. This is compounded - in the short term - by the fact that their useable stockpile of plasma is less than anticipated.

Concept of 'Self Sufficiency' in factor VIII

2. When BPL was planned 10 years ago, current demand was 10 million units. The plans for a new BPL forecast a rise to 100 million units. Current demand is circa 90 million and rising.

*or 100 million units - haemophiliacs*

3. The demand side of the equation is likely to go on increasing unless clinical practice changes; 100 million units remains a reasonable estimate of what 'self sufficiency' might necessitate in the near future.

*although the same max*

4. The supply side is mainly constrained by the availability of plasma, rather than the capacity of BPL.

*is also a factor*

5. The maximum practical plasma harvest will produce only some 71 million units at current yields.

*and the operation of plasma at capacity*

Earlier Expectations

6. Until very recently we believed 90 million units (i.e. self sufficiency at present levels of demand) was achievable next year and 100 million units was not beyond our grasp.

What has changed?

*and less than we had been led to believe were  
been achieved*

Two factors have emerged. Firstly, and most important, the yields being achieved in the new factory are substantially lower than expected. Secondly their useable stockpile of plasma is less than they thought.

Yield Problem

8. Self sufficiency at the 90 million unit level assumed a yield of around 180 units per kilo of plasma in the new BPL.

9. However this yield figure was one obtained in the laboratory and has not been achieved in the factory (either old BPL or new BPL). The new factory is producing a true net yield of 130 units per kilo.

*and was unfairly overoptimistic*

10. As recently as the 1988 Accountability Review CBLA was confident of achieving 166 units (the same as in the old BPL) but *and to* this has not been sustained in the new factory. They are actively pursuing higher yields. Their yields however exceed that of any commercial fractionator.

*do we know??*

Stock File Problem

11. The stockpiles <sup>was</sup> were planned to enable the new bigger factory to start full production whilst the NBTS was continuing the planned build up of its harvesting capacity. CBLA have under their new management team being introducing the sort of production accounting systems needed by a major plant. This work has turned up the fact that previously BPL had been recording the gross weight of plasma received (i.e. inclusive of packaging) and used that number for planning. As 'net weight' the stockpile has "shrunk" from 500 to 380 tonnes.

Effect of the New Assessment

12. The new yield figure would require a plasma harvest of 750 tonnes to achieve 90 million units. The NBTS maximum practical harvest is some 590 tonnes, producing 77 million units. The effect of the smaller buffer stock means that either a) NBTS must harvest 490 tonnes next year (out of the question); or b) BPL production must be restricted until harvesting catches up,

13. The best estimate is that we will have output of 65 million units in 1989/90 rising to 77 million by 1992/93. Thus we will remain short of 'self sufficiency' even at the current 90 million unit level of demand.

Responsibility

14. Before facing critics, see below, Ministers may want to consider whether CBLA have been culpable in any way.

Yields

X NO

you improved  
to me what  
being this

15. They will claim to have used the best estimates available at the time. They certainly had no incentive to be over optimistic. The product (factor VIII Y i.e. heat-treated) is relatively new and of course production in the new plant was an unknown quantity. Their estimates are now clearly proved wrong but it would be difficult to demonstrate retrospectively that they were in a position to have done better. They are taking active measures to improve yield but success cannot be guaranteed.

Stockpile

16. The confusion over the figures is hard to justify. It must however be said that it was the result of systems being installed by the new management that this came to light. The CBLA management do not underestimate the embarrassment and planning hitch this has caused.

Conclusion on Responsibility

17. I would suggest that however embarrassing these reassessments are they do not add up to a substantive case of mal management by the CBLA. There is no single cause and no tenable scape goat. Ministers might be best advised to close ranks with the CBLA and stress its positive achievements and its continuing efforts.

18. Privately however Ministers could well call in the Chairman and Chief Executive for a quick 'supplementary' review and make their displeasure clear.

HANDLING

19. We can expect a rough ride. The Haemophilia Society have only recently assured their members that there will be sufficient 'home grown' factor VIII by the end of 1988. They are unlikely to keep their disappointment to themselves and MPs are particularly sympathetic to their cause.

20. Rather than wait for this news either to leak out or be dragged out Ministers may wish to go on the offensive with an inspired PQ, (coupled with a meeting with the Haemophilia Society) which will assure MPs and the Society that all efforts possible are being made both to collect more plasma and to improve yields.

21. I would be happy to discuss.

M A Harris  
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