

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

Self Sufficiency in Factor VIII for Haemophiliacs

Your minute of 14 October refers.

SUMMARY

There are problems at BPL but these should not obscure its undoubted successes.

bit late!
was made? → 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.

The bad news:- The yields being achieved are however less than expected, and we will not be able to fully meet from UK sources 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 ^{annual} demand was 35 million units. The plans for a new BPL forecast a rise to 100 million units. Current demand is circa 90 million and rising.

NU ↓
haemophiliacs → 3. The demand side of the equation is likely to go on increasing unless clinical practice changes but 100 million units remains a reasonable estimate of what 'self sufficiency' for England and Wales might necessitate in the near future.

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

automatic max
5. The maximum practical plasma harvest will produce only some 77 million units at current yields.

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.

and less than we had been led to believe was being achieved

What has changed?

7. 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. (Earlier yield figures confusingly ignored pre-process plasma loss of around 7% and this gave a false basis for planning plasma needs).

we were led to believe more was being achieved

10. As recently as 12 July, when the 1988 Accountability Review took place CBLA was confident of achieving 166 units (the same as in the old BPL) but subsequently this has not been sustained in the new factory. They are actively pursuing higher yields. Their yields however exceed that of any commercial fractionator.

Stock Pile Problem

11. The stockpile was 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 been 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 true net 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.

14. The effect of the confusion over planning figures has therefore been twofold:

a) We have painted a falsely rosy picture on self sufficiency and coming clean will be politically embarrassing.

b) We did not put extra pressure on RHAs to wind up plasma harvests.

The effect of (b) should not be over exaggerated as RHAs were, in any case, reluctant to commit resources until the new BPL was able to give them product in return for their efforts.

Responsibility

15. Before facing critics, see below, Ministers may want to consider whether CBLA or particular officers have been culpable.

Yields

16. CBLA 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 guesstimates are now clearly proved wrong but it would be difficult to demonstrate retrospectively that they were in a position to have done better. The use of a figure for planning purposes which ignored pre process losses, is however hard to justify. They are taking active measures to improve yield but success cannot be guaranteed.

Stockpile

16. The confusion over the figures used for planning is again 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. The Authority's approach to planning has been slap dash and will cause embarrassment.

Adm Admin on Responsibility

18. Mr Hart and officials interviewed the Chairman (David Smart), who had sought reports from both the Chief Executive and the Director of BPL. The Chairman readily accepted that the slapdash approach to planning was inexcusable. The discussion concluded that prime responsibility must rest with the Director of BPL, Dr Lane. The Chairman has subsequently written confirming that disciplinary action (a severe reprimand) is being instituted. This seems an appropriate response.

David Hart, previously visited

BPL is in the throes of changing from a 'cottage industry' which grew out of a research laboratory to a multi million pound business. The new management systems being installed by the Chief Executive and the Finance Director will make a recurrence unlikely. Indeed it was the new systems which brought this farrago to light. The action proposed against Dr Lane will bring home to CBLA as a whole that they are now in a new era where management professionalism as well as medical/scientific excellence is a requirement of the job.

20. Any more severe action on Dr Lane personally could misfire by casting doubt by association on the quality of his professional work which underpins BPL's products. This would be totally counter productive. There has been much creditable world class work done at BPL under Dr Lane's management.

21. PS(H) is due to reply to CBLA's response to the post Accountability letter from PS(H). This will give her the opportunity both to demand new and cast iron figures from CBLA to replace those used for the Review, and to rub in the lessons about management matching scientific excellence.

22. If PS(H) wants to underline her concern even more, then this episode could justify an extra 'mini review'. However this might be a little heavy handed.

HANDLING

23. 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.

24. 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. They can also of course be reassured that the balance of needs for Factor VIII will continue to be fully met by imports which are now considered safe.

25. I would be happy to discuss.

M A Harris

AFH A406 GRO-C