Factrate Heat Treated Fls

HOUSE MESSAGE

C0000018/1

Armour Pharmaceutical Company Ltd.

R. B. C.
- 8 AUG 1985

To: D. Lewis
M. Cross
K. Dunbar
J. Vanhalle
M. Samuelsson

cc: A. Sheppard
J.D. Michelmore
R.B. Christie
L. Lucas
Master
Day
File

From: C.R. Bishop

Date: 7th August 1986.

Re: NEW HEAT TREATING PROCEDURE - FACTORATE AND MONOCLATE

I know enquiries to you regarding a review of our heat treating procedure have been increasing lately, especially with the annoucement in the Press recently (Guardian/New Scientist) wherein Dr. Michael Rodell declared this intent from the States.

In order to help you tackle these questions with some degree of credibility, the following should be the lines upon which your official response is made.

"As part of our ongoing Research and Development Programme, we are constantly reviewing all our product range in order to upgrade and refine the products. FACTORATE IP, in particular, has been upgraded in terms of purity over the last 12-18 months to the extent that we are now confident that an increased heat treating procedure will not result in product degradation or other adverse changes which could influence its safety or efficacy. In particular, there has been concern that attempts to decrease the risk of viral contamination of clinical factor VIII concentrates (for example, by heat or chemicals) might lead to changes in the antigenic determinants of factor VIII which could, in turn, result in an increase in the development of alloantibodies in haemophiliac patients. (Bird A.G. et.al. Haemophilia & Aids, The Lancet 1985 I:162-3).

Some studies are still to be completed, for example, individual countries half-life and recovery studies, but submission to the FDA for a product licence amendment is planned for September with approval likely in December. The new heat treating procedure will be 68°C for 72 hours in the dry state and product heated to this new procedure will, I would emphase, be both HIV antibody and ALT screened, and will be phased in during early 1987.

We would emphasise again that this move does not imply any lack in confidence in our current procedure (60°C for 30 hours) in terms of HIV elimination/inactivation, but is designed to improve still further the safety factor in the product in terms of total viral inactivation without the need for the addition of stabilisers which it is thought in themselves could protect virus as well as factor VIII activity."

Naturally, we have a considerable quantity of existing material in inventory and the last thing we need is for people to hold off ordering until the new product comes through.

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We would emphasise, therefore, that it will be a phasing-in process and not an overnight change and customers should understand this.

If there are any queries resulting from this information, please let me know upon my return from holiday but, hopefully, this statement will enable you to "scotch" any rumours as to our motives branded about by negative Directors or competition.

Regards,

GRO-C

C.R. Bishop.