Baxter

Interoffice Memorandum – For Internal Use Only

To: Patrick Rafferty - Egham Date: June 1 1990

From: Ron Feakes

Subject: Hemofil M

With reference to your note of 21st May 1990.

The area of personal representations and unlicenced products is one where great care must be taken in order to avoid breaking both acceptable Codes of Conduct (e.g. that of the ABPI) and the law itself. The Department of Health has, in the past, prosecuted companies for advertising unlicenced products.

Part VI of the 1968 Medicines Act (on Promotion of Sales of Medicinal Products) clearly indicates that only licenced products can be promoted and that the spoken word by Company Representatives constitutes a form of promotion. Moreover, the legislation under which we import Hemofil M (SI 1984-673) states the importer:

> "Will not at any time issue or cause another person to issue any advertisement or make any representation in respect of that medicinal product and that he will sell or supply that medicinal product only in response to a bona fide unsolicited order."

Thus your actions must be very carefully calculated such that you cannot be accused of promoting Hemofil M. This is doubly important as Baxter received a formal complaint from the DOH in early 1988 concerning our stand at the ISBT meeting held at Wembley late 1987 (promotion of Gammagard). Further transgressions could be very serious indeed.

To give you a frame-work in which to operate you must abide by the following rules:

i) The provision of factual scientific information in response to a request from a physician does not in itself constitute promotion. Therefore you should not offer such information until requested.

ii) You should not approach individual physicians with claims of safety for an unlicenced product. Such information must be made available through the Scientific press, by publication of data and substantiation by peer review.

iii) You should not set out to derogate other, licenced, products.

B02

iv) Discussing the therapeutic value of Hemofil M with a physician is only acceptable if it is the physician and not you who initiates the conversation.

Although this does limit you quite substantially, you should abide by these guidelines otherwise we could, at the very least, antagonise the Department of Health. This might in turn be detrimental to our Product Licence Application.

Going on to the availability of Hemofil M. When asked it is quite acceptable for you to inform the physician:

i) we hold small stocks in the U.K.

ii) the product is available on a named patient prescription basis

iii) the cost of the product

iv) contact names in marketing (for further information) and regulatory (for prescription release details).

Regards,

Ron Feakes