GRO-C

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Mr Thomson
Mr Angus
Extremely interesting.

CONFIDENTIAL

Mr D Macniven

Copy to: Dr MacIntyre
Mr Hamil

GRO-C

24 Nov 88

NATIONAL BIOLOGICAL STANDARDS BOARD (NBSB) AND NATIONAL INSTITUTE OF BIOLOGICAL STANDARDS AND CONTROL (NIBSC)

I attended the annual accountability meeting held on 23rd November between Health Department officials and the senior officers of the NBSB on the workings of the NBSB and its agent NIBSC. The performance in financial terms and in scientific terms over the previous year was reviewed and the 'action plan' for 1989-90 was discussed and eventually agreed. The Scottish end of NBSB and NIBSC is within my administrative bailiwick.

Three items on the scientific side are worth mentioning. Dr Schild the Director of NIBSC had in his programme for completion in 1992 a preparation of an international reference standard for rDNA produced factor VIII. He brought this forward to 1991 for completion since such products are already appearing on the market. He opined that by 1990 at the latest such a factor VIII would be freely available from the commercial market at a cost much less than the products currently extracted from human plasma. And of course it will be safer. P&C

Secondly they are very near producing a new method for detecting HIV in blood and blood products and it will be available shortly to detect very low concentrations in these products.

Thirdly with the help of Dr John Purvis (the pharmacist in charge of the biologicals product licencing section at Medicines Division) Dr Schild and his colleagues have produced in conjunction with the "National Blood Transfusion Service" guidelines which will enable the BTS to be self-regulating with regard to the standards relating to the processing of blood and blood constituents which are not licensable under the Medicines Act and the new EEC Directive on blood derivatives. NIBSC has a blood transfusion liaison committee which in turn has specialised sub-committees. It was not clear to me how fully the SNBTS was or is involved in these exercises but out of the meeting I got the distinct impression that Dr Cash was not happy that the SNBTS should be 'self regulating' and would prefer outside inspection. (By the by Dr Cash does not seem to be all that popular with NIBSC or with DOH!) ✓ [illegible]

You are maybe aware that there is a Biotechnology and Pharmacy Sub-committee of the EEC Committee on Proprietary Medicinal Products (a Committee set up under a previous Directive which directs the mechanisms used by member states to control the standards of 'medicinal products'

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sold on the EEC market). This sub-committee is the overseeing committee for all biotechnology 'medicinal product' license applications to the regulatory authorities of member states. Dr Purvis is the representative of the UK Government on that sub-committee which Dr Schild chairs (as an international expert). Both are, therefore, well placed to know what is on the horizon. Dr Purvis is a Scot, was a student of mine at Aston University and was for a short time on my staff at DHSS.

There were certain changes proposed in the financing of the NIBSC following the re-organising of the financing of the Medicines Division. The Medicines Division is to become the Medicines Control Agency on 1 April 1989 and all (or most) of its funds are to come from the licensing fees paid by industry. I will be minuting Mr MacKenzie and Mr Rushworth shortly on the possible effect this will have on our contribution to the financing of this NBSB and NIBSC.

GRO-C

GRAHAM CALDER
25 November 1988

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