A.

Dr D McInnes PS/CMO

From: D O Hagger MB1
Date: 5 June 1989
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BSE: HUMAN MEDICINES

1. It might be helpful to provide an up-date on progress over the precautionary measures being taken by the MCA in respect of human medicines sourced from bovine materials - my earlier minutes of 23 February (addressed to you) and 24 February (to Mrs Goldhill) refer.

2. Over 4,000 letters were sent by the MCA (then Medicines Division) to all licence holders for human medicines on 9-10 March 1989, enclosing copies of the joint CSM/VPC guidelines and a questionnaire, for licence holders to return by 1 May giving details of animal materials used in their products (annex A).

3. Now that most licence holders have replied the preparations for a full professional analysis are nearing completion. The enquiry has produced a lot of material which will take time to study before papers can be prepared for a meeting on 6 September of the special working group set up by the CSM to advise it (annex B). At this stage, a preliminary scan of the data has not identified any information which would appear to warrant immediate special action. The MCA is however taking account of the new guidelines in assessing applications for new licences and renewals.

4. In considering areas in which precautionary measures might usefully be taken, mention has been made of insulin prepared from bovine material. This is being borne in mind but it may to some extent be reassurring to know that such insulin is used in the UK only for a very small group of mainly elderly patients for whom it is difficult to switch to either porcine or genetically engineered insulin. Nevertheless, we are on the look out for any such products containing bovine brain or other possibly doubtful tissue.

5. Further progress reports will be supplied from time to time, the next after completion of the full analysis unless there is any major finding in the meantime.

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