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Your reference

Our reference

Date
14 February 1983

Dear George

SCOTLAND BLOOD TRANSFUSION SERVICE

I am writing now, as promised in Ian Brown's letter of 12th January, to deal with the policy points raised in your letter of 7th January and the report from the CSA.

There seem to be three main policy issues: i) the extent of the inspections; ii) the standards applied by inspectors, and iii) the question of manufacturing licences for Blood Transfusion Centres, and I will deal with them in that order.

The basis for the scope of inspections of Blood Transfusion Centres is the circular HSC(IS)144 and (I assume) its Scottish equivalent. This lists the "activities concerned with preparations of human blood which are medicinal products", and these are the areas to which the Inspectorate direct their attention during an inspection of a Blood Transfusion Centre. In brief, these "activities" include the manufacture and assembly (including a defined system of quality control), the contract manufacture and the introduction of new preparations of human blood and related products. The Inspectorate has therefore concentrated on these aspects. That is not to say that the Inspectorate will not have an interest in, for example, the source of the raw material but, for the foreseeable future, no extension of HSC(IS)144 is envisaged.

The aim of the first phase of inspections of Scottish Blood Transfusion Centres was to see that appropriate premises, equipment, procedures and staff existed and to provide a sound basis for future inspections. The same pattern is being followed in England and Wales. This was explained to all the Regional Directors and others at the time of the inspections.

On the matter of standards, the Inspectorate apply the same basic principles of good manufacturing practice to whatever pharmaceutical manufacturing activities they are inspecting, wherever the premises are located and whether the site is industrial or part of the NHS.

Specifically in relation to Blood Transfusion Service inspections, the standards looked for are the ones set out in the "Orange" Guide as modified by the "Red" Guide ("Standards for Collection and Processing of Blood and Blood Components").

In no instance are standards above those required. However, circumstances vary from Centre to Centre and methods other than those described in the guidelines but which achieve the same ends may be equally acceptable, as is recognised in the reports. This was the approach taken at the Scottish BTS inspections as it is for the BTS inspections in England and Wales, and as you know, the inspectors who visited the Scottish Centres welcomed the co-operation and assistance given to them during the period of the inspections.

Your references to "a predisposition to use inflexibly the general GMP provisions designed as standards for industrial pharmaceutical manufacture" and failure to recognise the "attributes" of blood products seem almost to suggest that because of the biological risks accepted by the product's use, we can ignore the microbiological condition of the incoming material, and the microbiological standards under which processing is carried out. I am sure you will agree that such a stance would be indefensible even if we could accept it.

The last main point is the question of manufacturers licences for the Blood Transfusion Centres. I confess to being somewhat bemused by the reappearance of this matter which I had thought settled some two years ago.

The issue of manufacturing licences for the Blood Transfusion Centres in Scotland when similar licences were not issued in England and Wales resulted, as you know, from differing legal advice in each case. Scottish law officers held that Crown Privilege did not apply and that licences were required; legal advice for England and Wales held that Crown Privilege did apply and that licences were not necessary. Licences were therefore issued for BTS Centres in Scotland but not for BTS Centres in England and Wales.

We were advised in 1979 (Mr Sutherland wrote to Mr Firstbrook) that the Scottish law officers had reviewed their original opinion and decided that Crown Privilege did apply to the CSA and Health Boards in Scotland, and that formal licensing of the Blood Transfusion Service in Scotland was no longer required. In other words from that time the BTS in Scotland was on the same footing vis-à-vis the Medicines Act as the BTS in England and Wales.

To save unnecessary paperwork on revocation or cancellation the licences issued in 1976 were allowed to run out. No new licences were required, although we had understood that SHHD proposed to issue letters of approval in all cases where under the original legal guidance, licences would have been required.

Against that background you can I hope understand why we thought that the question of manufacturers licences had been disposed of with the knowledge and agreement of all in Scotland who needed to know.

I am sorry this letter is rather long but it seemed important to deal with matters in some detail to dispel any possible misunderstanding. There still remains the question of the Compendium. I am advised that two copies were sent to Dr Moir, one before Christmas and another one in January. I hope that at least one has arrived by this time. It does not yet contain a section on Blood and Blood Products but this is being worked upon and something should be available - maybe in the form of an Appendix - within a year or two.

If you wish to discuss the contents of this letter I shall of course be very happy to arrange a meeting. If however you are content, we can now begin to think about an IAG meeting to discuss the individual Centre reports.

Yours sincerely

B K CHAMBERS