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MS(H)

From: Jonathan Orr, ICB
Date: 14 December 2001

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Mary Agnew, PS/PS(PH)
Olivier Evans, PH6.6
Charles Lister, PH6.6
Paul Brice, ICB
Tony Kingham, ICB
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Proposed European Blood Directive – further response to European Scrutiny Committee (ESC) required

Issue

Prior to the Health Council you wrote to Jimmy Hood MP, Chair of the ESC seeking scrutiny clearance on the blood proposal. This was granted although the ESC asked for the following further information:

"…..if a decision is taken at the Council on 15 November, we would be glad if the Minister could write to us again afterwards to inform us of the outcome."

Timing

The Committee next meets on 9 January 2002. Its Secretariat would therefore need to receive the letter on 4 January at the latest.

Recommendation

To sign the letter at annex A.

Your previous letter to Jimmy Hood MP, dated 12 November is attached at annex B, if needed.

Jonathan Orr
International Branch
Room 546
RH
x GRO-C

Annex A

Jimmy Hood MP
Chairman
European Scrutiny Committee
7 Millbank
LONDON
SW1P 3JA

Proposed Directive on Blood (EM reference: U/N of 24 October)

I was grateful that the Scrutiny Committee was able to consider and clear the proposed Directive on the quality and safety of blood in time for the 15th November Health Council.

As promised, I am writing to let the Committee know the outcome of the issue of blood in Health Council.

The main concern of the Government was to ensure that, whilst it supports the principle of voluntary unpaid donations, no binding requirement was made on Member States to obtain blood only from voluntary unpaid donations. The Government believes that it has achieved the aim of maintaining the right to import raw plasma for pooled products from the USA as a vCJD risk reduction measure. This has been made possible by the compromise wording found in time for Health Council (*The Common Position wording has not yet been ratified by Jurists-linguists or been officially published. The European Parliament is due to begin its second reading in January 2002*):

Article 4

1. **This Directive shall not prevent a Member State from maintaining or implementing on its territory more stringent protective measures which comply with the provisions of the Treaty.**

   In particular, a Member State may introduce requirements for voluntary unpaid donations, including the prohibition or restriction of imports of blood and blood components which do not satisfy such requirements provided that the conditions of Article 30 of the Treaty are met.

Annex A

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Article 19

1. **Member States shall encourage voluntary unpaid blood donations' with a view to ensuring that blood and blood components are in so far as possible provided from such donations.**
2. **Member States shall inform the other Member States and the Commission of the actions taken by them to achieve the objective set out in paragraph 1.**

Recital 22a)

According to Article 152(5) of the Treaty, the provisions of this Directive cannot affect national provisions on the donations of blood. Article 152(4) states that Member States cannot be prevented from maintaining or introducing more stringent protective measures as regards standards of quality and safety of blood and blood components.

You will note from the compromise wording that the UK is under no obligation to use blood solely from voluntary unpaid donations, although it is the case that all blood collected within the UK is of a voluntary and unpaid nature. Paid donations from the USA for raw plasma for pooled blood products are necessary as a risk reduction measure given the theoretical risk of vCJD.

Whilst the UK and all other Member States are now committed to informing the Commission of our domestic and policy arrangements, we do not believe that competence is ceded under Article 152(5) of the Treaty: this is a standard information exchange and is consistent with other arrangements already in place, such as the notification for communicable diseases.

The Government also shared the concerns of the Scrutiny Committee regarding the issues of hospital blood banks, the medical qualifications of the "responsible person" and the technical annexes and I am pleased to say that these issues were resolved satisfactorily at Health Council. Taking each of these in turn:

1] Hospital Blood Banks

As you know, our concern was that the original draft did not make it clear whether hospital blood banks were to be included in the Directive. We have consistently held and promoted the view that hospital blood banks should be covered by the Directive as they store and distribute blood. However, it would be disproportionate for all of the provisions of the Directive to apply to hospital blood banks.

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standards. This position has been reached at Health Council. The specific Articles which should apply to hospital blood banks were clarified and the Government successfully argued against the mandatory requirement for inspections every two years. It is believed that inspections every two years would increase the cost without improving standards, as well as being logistically impractical, and that such enforcement should be left to the competence of individual Member States.

2] Medical qualifications of the "responsible person"

Negotiations have been successful in loosening the definition, so that a three (and not four) year degree in medical or biological sciences and two years' practical experience is sufficient. A four-year science degree is much more common in other Member States than in the UK, and the Government believes that such a restriction would be disproportional to the requirements of the job. The Government opposed any further specification in the type of science degree, as the "responsible person" would have a predominantly administrative remit. We are satisfied that the UK interests have been met at Health Council.

3] Technical Annexes

As the Explanatory Memorandum dated the 26 February (Ref: 5773/01) pointed out, the Government did not support the original draft annexes on the basis that they were too prescriptive, would fall quickly out of date and would be difficult to translate into regulations.

However, whilst the Government did not support the original annexes, it also had reservations regarding the proposed amendment by the European Parliament. This proposed to delete the annexes in their entirety and to leave the entire drafting of technical requirements to the Commission and an expert working group nominated by Member States. It was felt that this was a step too far, as it would effectively give the Commission and its expert committee a *carte blanche*.

The UK has promoted a solution respecting the aims of the Directive and preventing the Commission from extending its powers without formal request. This compromise position was reached at Health Council on 15 November.

I am copying this letter to Lord Brabazon of Tara , Chairman of the House of Lords' Scrutiny Committee, to both Committee Clerks, Dorian Gerhold and Tom Radice, Les Saunders, Cabinet Office and Emma O'Sullivan, DH's European Scrutiny Co-ordinator

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Annex B

Jimmy Hood MP
Chairman
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7 Millbank
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12 November 2001

Proposed Directive on Blood

As you are aware, the Health Council is meeting on 15 November to agree a Common Position on the blood directive. I understand that your Committee has been unable to clear the proposal and is seeking clarification and reassurance in the following areas:

- unpaid donations and its effect on UK supplies from third countries;
- whether the proposal will apply to hospital blood banks;
- the medical qualifications of the "responsible person";
- the status of the technical annexes.

To take each of these points in turn:

Voluntary unpaid donations

There is a strong view among several member states that blood products should only come from voluntary unpaid donors. The UK Government supports this in priniciple, but it is regrettably impractical at the present time, given the theoretical risk of vCJD, and the need for the UK to import raw plasma for pooled blood products from the USA, where the only available supply in the quantities needed comes from paid donors.

The UK's key concerns are to ensure that the text of the Draft Directive provides sufficient flexibility for the UK to continue sourcing plasma from the USA, and that it is not drafted in such a way as to extend Community competence by regulating the way that blood supplies are sourced. Discussions on possible compromise texts are still continuing.

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The UK would support a solution which respects the aims of the Directive, and leaves to Member States to determine the mechanism for ensuring safety and quality standards.

The most important factor is the exclusion of blood banks regarding inspections and licensing. We hope that this will be adopted in the final text.

Medical qualifications of the "responsible person"

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