

PS(H)

From: Charles Lister PH6.6

Date: 26 October 2001

cc: see attached

DRAFT DIRECTIVE ON BLOOD

Issue

1. To agree a handling strategy for negotiations in COREPER and the Health Council on a proposed article in the Directive on unpaid blood donation.

Timing

2. A decision is needed by close of Monday 29 October to allow time to brief the UK representative for the Committee of Permanent Representatives (COREPER) meeting on 31 October.

Background

3. Earlier this week, you agreed documents for Parliamentary scrutiny on the Directive. The covering submission set out the remaining issues for negotiation including a proposed requirement on Member States to collect blood only from non-paid donors. This is a particularly sensitive issue for the UK because we currently import all plasma for pooled blood products as a vCJD risk reduction measure, and most of it comes from paid donors in the US.

4. The proposed requirement on unpaid blood donation was introduced into the Directive by the European Parliament at first reading stage in September. It is an issue that arouses a great deal of passion within Europe and has the support of a number of Member States. The argument, which is not proven, is that blood from unpaid donors is safer because paid donors are less likely to respond honestly when asked about risk factors that might bar them from giving blood.

Negotiating Strategy to Date

5. The Department's lawyers and Cabinet Office Legal Advisers are firmly of the opinion that such a requirement would be an encroachment on the UK's competence. Council Legal Services have not yet delivered a formal opinion on the issue but ~~the signs are that they are likely to agree.~~ [DQ: when is this expected?] This view is based on Article 152(5) of the Treaty which states that Community measures shall not affect national provision on the donation or medical use of blood. DH lawyers' view is that this protects not only existing national provisions on donation, but also any future provisions Member States might choose to take. Our negotiating position in Council Health Working Group has therefore been that no such requirement should be included in the Directive.

*previously
the have
indicated
that such
a requirement
should be
removed.*

Charles:

At European likely to have reserve.

- don't know Parliament

Min needs to get them on board

*It will go on in coreper and
very soon - but can reserve*

6. In the meantime, as a fallback position, we have looked for compromise wording on non-paid blood donation which would safeguard the UK's position. Our major concerns are that:

- there may be factors that override the safety gain from non paid blood donation, eg additional safety concerns such as vCJD or an inability to supply enough blood to meet the needs of the health service from unpaid donation alone. Nothing in the Directive should constrain the UK's freedom of action, now or in future, to ensure sufficient supplies of blood for the NHS or to protect the public health.
- Member States should be free to determine when it is justified to use blood from paid donors without prior reference to the European Commission.

We have yet to find a form of words that would be completely acceptable to us and to other Member States.

Decisions Needed

7. Much will depend ultimately on the view taken by Council Legal Services. But, in preparing our position for COREPER and the Health Council, we are faced with two options:

- to tolerate an encroachment on competence in order to safeguard the passage of a Directive we otherwise support; or
- to be prepared to threaten a challenge in the ECJ if the Article on unpaid donation is agreed against the wishes of the UK.

Consultation on either position will be needed with Ministers on the EP Committee and, if a threat is to be issued, the Law Officers would also need to be consulted.

8. Cabinet Office guidelines say that threats should only be made in the most exceptional circumstances as they may damage the UK's credibility. On balance, we would argue that exceptional circumstances do not apply in this case. [This view is supported by our Deputy Ambassador at UKREP who advises that]. We should aim instead to agree wording with other Member States that limits the encroachment on UK competence in line with para 6 above.

Conclusion

9. Given that anything agreed by the UK at COREPER cannot be reversed at Health Council, it would be helpful to know if you support the UK's proposed negotiating stance, namely that:

- our prime objective is to exclude any Article requiring non paid blood donation on competence grounds;
- failing that, we are prepared to agree to compromise wording that makes clear that there may circumstances where paid donation is justified and that decisions on this are not for the Commission to determine. This would involve a conscious

acceptance that UK competence had been broached and would require agreement with other Ministers.

10. If you are content, we will draft a paper for Cabinet Office to circulate to members of EP seeking agreement to this strategy in advance of the Health Council.

Charles Lister

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Ext **GRO-C**

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