

Alan Harvey

07/02/2000 16:52

Sent by: Alan Harvey/PH6

To: Mike McGovern/HSD1/DOH/GB@GRO-C
cc: Moira Wilson/IID-IB/DOH/GB@GRO-C
Pat Troop/DCMO/DOH/GB@GRO-C
David Hewlett/HSD1/DOH/GB@GRO-C
Laurence Knight/COMMS/DOH/GB@GRO-C
Alison Pitts-Bland/COMMS/DOH/GB@GRO-C
Tony Kingham/IID-IB/DOH/GB@GRO-C
Charles Lister/HSD1/DOH/GB@GRO-C
Gwen Skinner/HSD1/DOH/GB@GRO-C
Ailsa Wight/PH6/DOH/GB@GRO-C
Glyn Austin/PH6/DOH/GB@GRO-C

Subject: Re: FW: vCJD disease and donor exclusion cri

Mike

Sorry, a question I should have asked in my last e-mail. In the CPMP and BWP, what kind of comitology model applies? If the Commission *formally* propose something, does it need a unanimous block of member states to oppose, or is it simple majority? Will there be a vote on 18.2.00 on the 'final version of the survey questionnaire' or will that happen later, if so can we best-guess when? Can we take it that the aim at the moment is to engage the Commission and persuade them to step back from going down this road - and can we assume that things are not so far down the track that it is not too late to do so?

Might it be worth seeking a bilateral with DGV in trying to head this off, or would that backfire?

Alan Harvey

Mike McGovern



Mike McGovern

07/02/2000 13:32

Sent by: Mike McGovern/HSD1

To: Moira Wilson/IID-IB/DOH/GB@GRO-C
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Ailsa Wight/PH6/DOH/GB@GRO-C
Alan Harvey/PH6/DOH/GB@GRO-C

Subject: FW: vCJD disease and donor exclusion cri

Moira and copyees

Alan Harvey

07/02/2000 16:42

Sent by: Alan Harvey/PH6

To: Mike McGovern/HSD1/DOH/GB@GRO-C
cc: Moira Wilson/IID-IB/DOH/GB@GRO-C
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Ailsa Wight/PH6/DOH/GB@GRO-C
Glyn Austin/PH6/DOH/GB@GRO-C

Subject: Re: FW: vCJD disease and donor exclusion cri

Mike

Thanks for this. In view of the importance of this development, I have taken the liberty of alerting other arms of the SEAC Secretariat in both MAFF and JFSSG.

Alan Harvey

Mike McGovern

► Mike McGovern
07/02/2000 13:32

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Alan Harvey/PH6/DOH/GB@GRO-C

Subject: FW: vCJD disease and donor exclusion cri

Moira and cpyees

You will wish to be aware that the EC are considering deferral of UK donnors and those who have lived in the UK during the time BSE was epidemic because of the theoretical risk of transmission of vCJD. This follows the FDA and Canadian decisions last year. Despite all Member State experts 9 apart from Austria) indicating that this should not be done in response to a 20 question survey, the Commission are pushing ahead using CPMP and the BWP. The UK is in a difficult position because opposition on our part is likely to cause political flack and risk the re-accusation that we caused vCJD by adopting the same negative approach to regulation in the past. And in any case there is no further action we will need to have to take.

In effect we have done all we can nationally. And as recently as last September/October CSM and SEAC indicated that no further action was required to reduce the risk of vCJD transmission through the blood and blood products in the UK. However MSs may feel exposed by the regulatory action taken by other countries including US, Canada, New Zealand Japan and Israel....though the push is not coming from individual MSs but the EC.

CPMP and DG SANCO (formerly DGV) -the DG which now has responsibility for blood safety are combining with the CPMP Biotech Working Party (BWP) to carry out a survey of travel within the EC between Member States and the UK with a view to developing deferral criteria. These would need to balance the impact of any such restrictions on the availability of blood to national populations against the theoretical risk of transmitting vCJD in this way.....the impact of US type regulation for example would rule out about 60% of the Irish Republic's donors, and up to 20% of those in France.....and of course 100% of those in the UK!!!!!!!!!!!!!!

There is great concern about the wisdom of this action, the logic behind it, the science such as it is and the media impact on public opinion and voluntary blood donation.

I would be grateful if in the first instance UKREP could be apprised of this proposed EC action and there may be a need to inform our embassies of the potential political/media attention.

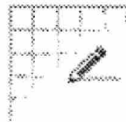
I attach our lines to take.

Mike McGovern



lines to take feb 200

----- Forwarded by Mike McGovern/HSD1/DOH/GB on 07/02/2000 12:51 -----



Lincoln Tsang
07/02/2000 11:16

Sent by: G=Lincoln/S=Tsang/OU=MSMAIL/O=MCA/P=MEDCONTROLUK/A=CWMAIL/C=GB

To: Mike McGovern/HSD1/DOH/GB

cc: /G=Frances/S=Rotblat/OU=MSMAIL/O=MCA/P=MEDCONTROLUK/A=CWMAIL/C=GB

Subject: FW: vCJD disease and donor exclusion cri

Mike
for your information.

Lincoln

-----Original Message-----

From: Simona.Villa@GRO-C

Sent: 03 February 2000 14:05

To: Tsang, Dr Lincoln; a.baeckmann@GRO-C, cpini@GRO-C
es@dkma.dk; gerhard.beck@GRO-C, bio@GRO-C, scmlns@GRO-C
jeanmarc.spieser@GRO-C, mats.welin@GRO-C
roland.dobbelaer@GRO-C, Maurice.Robert@GRO-C
papmail@GRO-C, Pekka.Kurki@GRO-C, Ronald.Haigh@GRO-C
vincent.irwin@GRO-C, anna-kristin.rolstad@GRO-C, ingrid.Hegger@GRO-C

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ttifv@GRO-C, jhtfr@GRO-C, seira@GRO-C
Subject: vCJD disease and donor exclusion criteri

Dear Colleagues,

At their January meeting, the CPMP agreed that the survey on the travel patterns of European donors to the UK be carried out using a harmonised questionnaire. This issue is now on the agenda for the February BWP meeting when the objectives will be:

1. To reach agreement on the key common elements (i.e. time periods for stay in the UK) for the questionnaire to ensure that results from the individual Member States can be compared.
2. To estimate when results of the surveys will be available in order to commence organisation of follow-up meeting.
3. To consider scope of the follow-up meeting. An update meeting with a similar format to the TSE meeting held in January 1999 is suggested. This meeting would concentrate on human TSEs.

The papers have been circulated in the pre-meeting post and the French questionnaire was also sent on 13 January.

We have heard from DG Sanco (Health and Consumer Protection) that this issue has been discussed with Commissioner Byrne. They have been instructed that DG Sanco, in close cooperation with DG Enterprise, should take the lead and distribute the final version of this survey questionnaire during the next meeting with blood experts on 18 February. (The survey questionnaire would clearly reflect the role of the EMEA/CPMP).

Since the February BWP and CPMP are prior to the DG Sanco meeting, this should allow us to provide DG Sanco with our recommendations for the questionnaire in advance of their meeting.

With best wishes,

Glenda Silvester