Wider Implications Ala.

Falconer S (Sandra)

From: Stock RG (Bob)
Sent: 17 December 2001 13:58
To: Keel A (Aileen); Lindsay SG (Steve); Scott WS (Will); 'Angus Macmillan Douglas (SNBTS)'
Cc: Whittle P (Pam); Falconer S (Sandra); 'Ranald Macdonald (CLO)'; Palmer DJ (David) (Health Finance); Beaton P (Peter); Naldrett CA (Chris)
Subject: Revision of the General Product Safety Directive

I have received a copy of a DTI consultation document on the above (the Directive from which CPA is derived) - requesting comments by 8/3/02.

The revised directive has to be transposed into UK legislation and the document seeks views on how best to achieve this. If anyone wants to see the whole document I suggest they approach DTI directly at the Consumer Affairs Directorate (020 7215 6740) requesting CA 009/01 "Transposing the revised General Product Safety Directive" .
At a quick reading there are a number of issues that are of potential interest to us, as follows:

Risk Management

Breaching the existing provision to 'provide consumers with information on risk and to adopt measures relating to risk management' does not of itself create an offence - the document poses the question as to whether it should become so.

Tracing the origins of products

The revised directive requires producers to 'keep and provide the documentation necessary ' to allow tracing of products 'in proportion to their respective responsibilities'.

Penalties

The question is posed as to whether it might be appropriate to provide a route for civil redress eg 'by creating a statutory duty , the breach of which would allow consumers to take legal action'.

There are some other issues that don't seem to have a direct effect on us (although others may see it differently) - in particular, supply of products 'in the context of a service', and provisions for recall of defective products.

I'd be happy to copy discrete sections to anyone who is interested.

BOB

Wider Implications

SCOTTISH EXECUTIVE

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19 November 2001

Dear Bob

I apologise in advance for the time it has taken for me to respond to your letter of 5 October on the EOR evaluation of the risk of transmission of vCJD by transfusion, and in particular the reaction of members of the Clinical User's Group to this data. It is probably worth restating that the EOR work is being carried out in an area where the risk currently remains **theoretical**. There is no evidence that any form of CJD, including vCJD, has ever been transmitted by blood transfusion. The EOR assessment is therefore founded on an assumption about the potential size of the initial vCJD outbreak. As your letter acknowledges, estimates of risk based on such assumptions are necessarily limited.

However, SEHD is taking the issue of communication of risk in this and other related areas extremely seriously. Following the Burton Judgement on Hepatitis C in England earlier this year, we have committed ourselves to looking at how we communicate risk across the whole of health care. This work is being led by my colleague Bob Stock to whom I am copying this letter. In addition, SNBTS are already well advanced with "repositioning" themselves in terms of communication of blood transfusion risks. This work is informing the wider Departmental work to which I have referred.

The other relevant development in this area is the framework which has been drawn up by the CJD Incidents Panel to guide NHS organisations on the management of incidents where patients have possibly been exposed to CJD or vCJD in health care settings. The framework has 4 main elements:

- The evidence base supporting the need to take measures (although given current knowledge of vCJD, this incorporates a range of assumptions based on limited clinical, epidemiological and research findings).
- The public health investigation of such incidents.
- The management of incidents involving surgical instruments and blood or blood products.
- The mechanisms for making the public aware of such incidents.

AHG115111

The UK-wide consultation on the framework started on 10 October, and the document can be accessed on the website http://www.doh.gov.uk/cjd/consultation. One of the expected outcomes is that we will collaborate with DH England on developing an appropriate campaign to increase public awareness of these incidents. The framework has been widely disseminated to professional and patient groups, and I know that the Panel would be delighted to receive comments from you either as an individual, or on behalf of the Clinical User's Group. It may be that we should have this as a formal agenda item for the meeting of the User's Group on 14 December.

I hope that the actions outlined in this letter will reassure colleagues on the User's Group that SEHD is taking the issue of communication of risk of transmission of vCJD by transfusion extremely seriously.

Kind regards,

Yours sincerely

DR A KEEL
Deputy Chief Medical Officer

cc Mr R Stock

AHG115111

File. Wider implications

1. Dr D Jefferys (Agreed)
2. Lord Hunt

From C S Bray
Date 17:10/01

Cc: Christopher Cox APS/PS(L)
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Designation of Medical Devices as "Single Use"

1. Purpose:

(a) To highlight the anomalous position whereby manufacturers designate some medical devices for "single use", which are then routinely re-used in the NHS.

(b) To seek your comments and agreement to the proposed strategy.

2. Timing:

Non urgent, but we understand this subject could be raised at the next Health Council for discussion by the Belgium Presidency under the issue of Medical Appliances.

3. Background:

3.1 A significant number of medical devices are placed on the market with the "single use" designation. The manufacturers of these devices, some of which are supplied sterile, are required under the provisions of the Medical Devices Directive (93/42EC) to carry out a risk assessment in order to CE mark the product. In some cases there

will have been a Notified Body assessment of the manufacturer (for example if the product is supplied sterile, or if it is a Class 2A product , or higher). The operation of the Medical Device Directive places the responsibility for the designation of use of the device with the manufacturer. Medical Devices are controlled through the internal market regulation whereby once they are CE marked in any part of the European Economic Area they can freely circulate.

3.2 Where products are labelled for "single use", this indicates that the device cannot be safely re-used, for example the material cannot be re-sterilized or the performance of the reprocessed device cannot be guaranteed. For these products the "single use" designation is essential and the product must only be used on one occasion for one patient and then discarded.

3.3 MDA's advice and the current NHS Controls Assurance Standard makes it clear that the NHS must follow these designations in the interests of patient safety. There are also potential liability issues if users ignore this information.

3.4 However, some categories of products are also marked "single use" which, despite the designation, are typically re-used in the NHS. Re- use can take the form of multiple use on a single patient or re-use with different patients. Manufacturers of such products frequently know that their products are being used more than once, and some give "off label" advice on re-use.

4. Issue:

4.1 Single use anaesthetic breathing systems provide an example of the problem, which we are facing. The users are well aware of the increased liability they face in the event of an adverse incident resulting from re-use of a device marked "single use". In order to protect the breathing system from microbial contamination a new bacterial filter is used with each patient – thus minimising risks of cross infection.

4.2. Users are increasingly challenging the "single use" designation for other products, for example external fixation systems, suction tubing, etc. They feel certain that some manufacturers choose this route to improve sales and to avoid the costs and inconvenience of validating re-use instructions and to limit liability.

4.3 The recent tragic death of a young boy in Essex has brought the re-use of anaesthetic breathing systems into high profile. Whilst this specific incident could not be related to re-use, nevertheless the press raised this as a potential problem.

4.4 The reasons for re-use of these items are :

1. Users do not consider there to be a risk to patients, providing bacterial filters are used.
2. Cost
3. Supply problems (industry could not meet demand if all "single use" breathing systems were used once only.
4. Storage and disposal logistics
5. Reduction in throughput of cases – a full system check should to be carried out each time the system is changed.

4.5 There is a need to better label products with clearer instructions for use. The "single use" designation is essential for certain products. Users must be trained that this means these products should be used once and then discarded. However, use of the term should be restricted to those devices where it can be justified.

5. Immediate and Future Action:

5.1 MDA has already had discussions and held a meeting with manufacturers of breathing systems and representatives of the anaesthetic profession. This has led to manufacturers collecting further evidence about the risks associated with re-use. Two companies are now considering amending their instructions for use to permit safe re-use of the device. Once key manufacturers have moved on this issue, market forces will then drive this section of the industry. We are already taking the matter forward with the NHS Purchasing and Supply Agency who have been involved in these discussions. This debate may need to be widened to include manufacturers of other medical devices.

5.2 For products where there is little competition and where we are not able to convince manufacturers (unwillingness on their side, overseas manufacturers etc) there is little we can currently do through the regulatory mechanism providing the manufacturer and the notified body have met their obligations under the Directive. One way to progress the issue for these products is by involving Europe.

5.3 In 1999 Belgium made a proposal to introduce a National Decree, requiring manufacturers to justify the use of the "single use" designation. At that time, this was overwhelmingly opposed by Member States, including the UK, and the Commission. We understand that the issue might be raised at the November meeting of the Health Council, and opinion on this matter could be changing.

5.4 In the event of a consensus within Member Sates to take action, it is possible that this could be achieved via a mechanism that does not require a change to the Directive.

6. Recommendations:

- MDA will provide briefing for the Health Council on this matter if it is placed on the Agenda.

- MDA will continue to pursue the issue of re-useable breathing systems with manufacturers, involving representation from the anaesthetic profession and PASA. This voluntary approach has a reasonable chance of success, because it involves a competitive market and a number of manufacturers have indicated their willingness to re-consider the designation of their devices. We will report back to Minister on the progress of these discussions.

- If this is not on the Agenda, then we recommend that the UK does not raise the issue at this stage. Rather we should assess the response to our initiative with manufacturers and in light of this put a further submission to you. A possible subsequent way forward would be to develop a policy paper to be put to the

Competent Authority meeting under the Spanish Presidency followed by further discussion in the Medical Device Experts Group, chaired by the Commission.

Are you content with the above recommendations?

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