

**MINUTES OF THE COMMITTEE ON THE SAFETY OF DEVICES MEETING:
23 MARCH 2006**

Members Attending:

CSD

Mr John Williams (Chair)
Mr Guy Alexander
Dr Anna-Maria Belli
Dr Steve Bennett Britton
Miss Catherine Cairns
Mr Christopher Earl
Prof Karen Facey
Mrs Sheila Fisher
Mrs Christine Glover
Dr Julie Kent
Prof Ian Kimber
Prof Ian Learmonth
Prof Peter O'Donovan
Dr John Perrins
Dr Geoff Ridgway
Dr Charles Sears
Prof Irving Taylor
Dr Gary Thorpe
Dr John Turney
Dr Carl Waldemann
Dr Gordon Watkins

MHRA

Dr Susanne Ludgate
Dr Tom Clutton-Brock
Mr Jonathan Plumb
Mr Philip Grohmann
Mr Andrew Crosbie
Mrs Valerie Field
Mr Alan Lynch
Mr Andrew Marsden
Dr Catriona McNie
Ms Louise Mulroy
Mr David Grainger
Mr Mike Peel
Mr Richard Woodfield
Mr Sean Fletcher

DH

Prof Sue Hill, Chief Scientific Officer

Devolved Administrations (Observers)

Dr Michael Cornbleet, DHSS, Scotland
Mr Andrew Wong, Scottish Healthcare and Supplies
Mr Peter Philips, Surgical and Materials Testing Laboratory, Wales
Mrs Elizabeth Qua, DHSS, Northern Ireland

Industry (Observers)

Mr Ray Hodgkinson, BHTA
Mr Mike Kreuzer, ABHI

1. WELCOME

1.1 The Chairman welcomed everyone to the Committee meeting.

2. APOLOGIES

2.1 Apologies were received from Mr Arvind Singh and Professor David Sharpe.

3. MINUTES OF LAST MEETING

3.1 The minutes of the last meeting were agreed and will be posted on the MHRA website.

4. MATTERS ARISING/ACTION POINTS

4.1 Diathermy: There is a two pronged action aimed at clinicians and manufacturers. There have been discussions with manufacturers about relabelling the maximum setting on the dials of existing diathermy equipment. At the moment the maximum power output is variable amongst different manufacturers. Secondly, MHRA will be exploring how the Standard on diathermy could be altered to address the concerns of surgeons. There will be a meeting on 24 March 2006, with industry and clinicians, to discuss.

4.2 Health Care Industry Task Force Communication Groups: **Dr Ludgate** has been in talks with the task force to produce information aimed at informing healthcare workers and professionals of the functions of MHRA and the regulation of devices.

4.3 Blood Safety Regulations, Haemovigilance and upgrading of the website: **Mr Bray** updated the Committee. A system to report serious adverse reactions (SAR) and serious adverse events (SAE) is in place, and reports have doubled. Feedback is that the system is delivering what it is supposed to deliver.

4.4 Problems associated with the purchase of medical devices from eBay: Dr Ludgate reported that the MHRA has inserted a paragraph on the eBay website explaining the legal background for the purchasing of medical equipment. If any members of the Committee encounter any products on eBay which cause concern, they should notify the MHRA.

4.5 Clinical investigation audit: The Chairman confirmed that those members who were not involved in the audits last year, would be high on the list for audits to be conducted this year. They are currently trying to determine dates to conduct further audits. Once again, the audits will be conducted using teleconferencing.

4.6 The setting up of a converging technologies unit: The Chairman deferred this issue as the relevant people were not present.

4.7 Royal College of General Practitioners' proposed general practitioner curriculum: The Chairman wrote to the College and had received a sympathetic response.

5. PAYMENT FOR ATTENDANCE/CSD AUDIT

5.1 The Chairman brought the attention of the Committee members to the claims envelopes prepared by Mr Peel.

5.2 He apologised for the fact that a number of members had not received their payment, however, as they now all had the correct forms this would hopefully reduce the problem.

5.3 If anybody had any further problems, they should contact Mr Peel.

6. CONFLICT OF INTEREST: REMINDER

6.1 The Chairman informed members of the need to declare conflicts of interest. He asked whether any member had a conflict of interest with any of the day's agenda items. None were declared

7. MAIN ITEMS

7.1 Communications with the Health Service: CSD: 06/006

Mr Grohmann presented this paper in conjunction with a CD containing samples of safety warnings and other publications which were provided to members prior to the meeting. The CD contained examples of Medical Device Alerts (MDAs), posters, a targeted letter, a Device Bulletin and one-liners.

The Committee was asked to comment on the clarity of the message; the quality of the information included; the appropriateness of the targeting of healthcare professionals; and in respect of MDAs, the appropriateness of the Safety Alert Broadcast System (SABS) deadlines that have been set. The Committee was also asked whether they could suggest any alternative (better) ways of communicating with healthcare professionals.

A wide ranging discussion followed the paper. Bulletins should remain a priority as they are very useful when out in the field. It was suggested that pictures, diagrams or technical descriptions would aid understanding. This is something that the MHRA considers if it will enhance the message, however, the size of the image can be an issue if the message is going out via email.

There is a perception that the Agency is reluctant to mention individual products and names. This reflects an inappropriate approach to risk. It was explained that when there is a specific issue with a product, names are used if required. Names are not used, however, when there is a more generic problem. It should also be borne in mind that before naming a manufacturer, their consent is first required. This can cause delays in getting a message out.

The receipt of messages is monitored through the Safety Audit System. In care homes it is more difficult to establish that the message has reached the relevant people. There are discussions with the Department of Health about extending the SABS system.

A Committee member tested pink communications on some primary care colleagues. Their reaction was positive, however, it was suggested that the subject be emboldened. It was also suggested that consideration should be given to producing these communications for patients.

When communications are sent via email, it was suggested that providing a link rather than the actual file might be useful. By providing a link, the downloading of information would be detectable off the server. This could provide information on uptake. It was also suggested that sending messages via text could be useful. This is a system used by the FSA.

There is a lot that might still be done, but the Committee applauded what has already been achieved.

7.2 Actions to address Health Service misunderstandings – single use devices: CSD: 06/008

Ms Mulroy highlighted the problem of misunderstandings in relation to the term and symbol for single-use devices. Single-use devices should never be re-used, but this message does not appear to have reached healthcare professionals.

The Department of Health has conducted research which established that 62% of respondents reported the re-use of single-use devices. There is also a perceived lack of risk associated with single-use device re-use. Similar research conducted in Germany and China also found that approximately 70% of experienced ICU nurses and doctors did not understand the single-use symbol.

The Single-use Medical Devices: Implications and Consequences of re-use DB2000 (04) was issued in 2000 but is currently being updated for publication in March 2006. In addition to this, the MHRA proposes issuing a poster to highlight this issue and to raise awareness of the symbol and the associated risks.

The Committee was asked to comment on the proposed action to issue a poster, the content and design of the proposed poster and whether there is any further action that could be taken.

The production of a poster was endorsed by the Committee. A number of suggestions were made in relation to its clarity. Rather than clarify the situation, it appeared that the final sentence confused the matter further. There is also no explanation of what the two pictures in the poster are. There was a suggestion that they should be moved up to disassociate them from the final sentence.

The single-use symbol is misunderstood and confusing. It is an international symbol, therefore, it was recognised that it would be difficult to change. If, however, it could be changed, it should be changed. In the context of the poster, the symbol should be made more prominent e.g. printed in red.

It doesn't save money to re-use a device as there are costs involved in cleaning, decontaminating and sterilising devices. There is a need to make the point that single use can be cheaper, and can sometimes be the only safe practice. It was pointed out that for trusts reprocessing products, they are taking on the role of a manufacturer and thus attracting the liability of a manufacturer. This angle could act as a deterrent to the reprocessing of devices.

There are numerous other symbols used in the context of devices which many people do not understand either. As well as producing a poster, the production of a booklet containing other symbols may also be useful.

7.3 The challenge of communicating safety advice to care home staff: CSD: 06/009

Mr Plumb and Mr Marsden presented this paper to the Committee.

The example of communicating the safety of bed rails to care home staff was used. Bed rail incidents mainly occur in private nursing and care homes. It is a challenge to ensure that safety advice and warnings reach the intended audience and that it is acted on in care homes.

The Safety Alert Broadcast System (SABS) does not include the care home sector. The Department of Health funds The Commission for Social Care and Inspection (CSCI) to distribute the MHRA alerts. To date this has primarily been by post. CSCI are currently rolling out electronic delivery of safety information, similar to SABS. This has the potential to make improvements in reliability and the speed of delivery of safety advice.

In October 2005 the MHRA consulted with stakeholders on the appropriateness of its past advice. The overall response was that the advice is workable and effective but must be kept “live” and thus should be updated. There are a number of proposed actions for the future which include updating and amending Device Bulletin DB2001(04), compiling a one-liner publication on bed rails for care homes, to write a series of articles on safe bed rails use and to issue a new poster.

The Committee was asked to consider whether the proposed actions are proportionate and likely to be effective, and whether there are further actions that the MHRA should undertake to ensure that information remains “live” and pertinent to staff in this sector.

In discussion it was stressed that it must be ensured that bed rails are not viewed as a bad thing. It was suggested that the messages should not be restricted to care homes as a member was aware of a trust which had banned bed rails.

Education will play a major role. GPs can identify problems and bring them to the attention of the care home provided they are aware of the potential problems. It has become clear that the inspectors themselves are not clear on what to look for as there has been a demand from inspectors wanting teaching sessions.

7.4 Planned changes for Assistive Technology: CSD: 06/010

Mr Lynch updated the CSD on the planned changes within Devices Division for Assistive Technology (AT).

More than 4 million disabled people in the UK use AT. These numbers continue to grow as the population ages and more people continue to live independently in their homes. Users range across all age groups.

There have been a number of recent major plans and reports which have highlighted the area where AT will have major effects on the future of healthcare, for example, the NHS Improvement Plan and the Healthcare Industries Task Force (HITF) Report of November 2004.

Stakeholders representing, amongst others, the electronic assistive technology services, the Royal College of Physicians, BHTA and Empower have all expressed a wish for the Devices Division to improve on the present fragmented approach to AT with the MHRA by establishing one specific AT unit.

MHRA has agreed to combine the 2 units that presently cover these devices to form a new unit for Assistive Technology (AT) managed by the MHRA centre in Blackpool. This will take effect from 3 April 2006. This will provide a single point of contact and expertise for stakeholders, a single unit which will be better able to support relevant policy units and a single unit investigating all adverse incidents concerning AT.

The CSD was invited to note the changes and to raise any subjects that they felt worthy of further discussion in assisting the new unit to move forwards in the future.

Current ideas on the way forward are to raise awareness of the MHRA and the new AT Centre; to improve adverse incident reporting from users and carers; to improve training of therapists; to highlight safety issues and the reporting of adverse incidents.

Projects currently underway include: the preparation of a press release; working with the College of Occupational Therapists; providing input to the MSc in Assistive Technology at King's College; ongoing liaison with Empower (user group); ongoing liaison with NHS groups and ongoing liaison with the main trade association, BHTA, including participating in training sessions.

Some ideas put forward during discussion included a suggestion that manufacturers should enclose a card with the product giving information on what to do if there is a problem with the product. It was also suggested that community matrons should be considered as they manage people with complex disabilities, yet it is doubtful that they would receive much training on AT.

A matter not directly in the remit of the MHRA was raised in relation to the funding by the NHS of devices for children and the delays that are encountered. Mr Lynch confirmed that there are two groups looking at this matter and agreed to pass on the details following the CSD to the member concerned.

7.5 Problems of metal hip replacements: further action: CSD: 06/007

Before the paper was presented, the Chairman stressed the importance of confidentiality in respect of this matter. It is an extremely sensitive topic, therefore, anyone who felt they were unable to keep this matter completely confidential was asked to leave the room. All members remained.

This paper was presented by Mr Crosbie as an update to the Committee. There is a growing concern over the biological risks of metal wear debris released from orthopaedic metal implants, especially from so-called metal on metal hip implants. There is evidence to suggest that some metal on metal hip

replacements may be associated with increased DNA-changes, which might result in genotoxicity in patients.

Following on from advice from the CSD, a paper was prepared summarising the DNA-changes found in patients with metal, weight-bearing orthopaedic implants and presented to the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM).

COM acknowledged the reports but stressed that it was not known whether there were any clinical implications of the findings. COM requested more clarification on the methodology by contacting the concerned authors and an update on the matter will be presented to the next meeting.

A discussion followed the paper. Lack of long-term experience is one of the factors driving concerns. In the past these devices were inserted into mostly older people with no adverse clinical reports. They are now being inserted into younger people. Therefore, more adverse clinical reports could be reported as they may only become evident in the long term and may only affect the more physically active patients. A risk benefit analysis will have to be incorporated into any assessment.

CSD discussed whether it would be in the patient's interest to issue advice to the public at this stage. Consensus was reached that the benefits of such implants are real, whereas the discussed risk is theoretical and currently unquantifiable but definitely low. Also, currently no useful clinical advice could be given. However, any advice would raise the profile of the issue, which could cause needless distress to those who already have metal on metal implants.

Metal on metal is most used in the younger, more physically active patient groups. There might be implications for other metal implants of similar alloys that produce wear debris.

7.6 NICE document

The Chairman brought the NICE document to the attention of the Committee. He requested members to read it and provide comments to either himself or Dr Ludgate within the week.

8. REGULATORY UPDATE

8.1 Physical Agents (EMF) Directive: CSD: 06/011

Mrs Field and Mr Grainger provided an update to the Committee.

HSE organised a discussion on this issue in January 2006. Representatives from the MRI manufacturers, government organisations, research organisations, charities and professional bodies attended. A draft report (available from Mr Grainger) has been produced which makes the following main points:

- the proposed limits were based on limited and dated research
- there is no data on occupational exposure received by staff working near to MRI units and that research is urgently needed to determine if current exposure is near to, or above the proposed limits

- what research should be undertaken and who should fund it
- it would be very difficult to get an exemption for MRI from the directive, but work on standards by the International Electro-technical Commission (IEC) may be a route to take
- the directive should not be seen by the public as an indication that MRI was unsafe

Updates since 24/2/06:

- research (Progress in Biophysics and Molecular Biology 87 (2005) 267-278, Numerical evaluation of the fields induced by body motion in or near high-field MRI scanners, Stuart Cozier, Feng Liu) has been found which indicates that the Directive will have implications at 1.5 Tesla (Currents induced by movement through the Static field);
- representatives from the Royal College of Radiologists have recently met with the European Social Affairs Commissioner Spidla. They were informed that there is to be an EU working party to review the impact of the Directive on MRI;
- the use of MRI equipment and the EU Physical Agents (Electromagnetic Fields) Directive has recently been a case study for the Select Committee on Science and Technology looking at "Scientific advice, risk and evidence: how Government handles them". There has been a joint submission from professional bodies (RCR, BIR, IoP, IPEM and ISMR

HSE has formed a small working group to take forward proposals, and the MHRA has been invited to participate.

The Directive does not cover exposure to patients. It has to be transposed into UK law no later than 30 April 2008. It will have significant implications for all establishments using MR. HSE is the government lead.

HSE hopes to do quick research on this issue.

The Committee felt that this was brought to its attention too late. It was explained that this Directive came from Europe with very little involvement from the UK. The Directive will be run by DTI and given to HSE so it is a complicated chain and, therefore, difficult to get in early.

The Chairman asked that the Committee be kept informed of developments.

8.2 Mercury Directive: CSD: 06/012

Currently mercury-in-glass thermometers and sphygmomanometers may still be used provided users follow the Control of Substances Hazardous to Health (COSHH) Regulations.

The European Commission is proposing to restrict the marketing and use of all mercury devices. The MHRA has briefed the UK representative to request that exemptions should be allowed for use of mercury in glass sphygmomanometers for health care use while alternative methods are established.

DEFRA is the lead department with the MHRA liaising closely as it will directly impact medical devices that currently use mercury, mainly sphygmomanometers, fever thermometers and dental amalgam.

Sphygmomanometers and fever thermometers – restrictions may apply to the marketing of all mercury fever thermometers and measuring devices containing mercury for consumer use. The scope is not yet finalised but it is likely that the marketing of all fever thermometers will be restricted to both consumers and professionals. In addition, it may be expanded to include restrictions on sphygmomanometers for healthcare use. However, there may be exemptions where adequate alternatives are not yet available.

Dental amalgam – the Commission will ask the Medical Devices Expert Group to consider the use of mercury in dental amalgam with a view to considering whether additional regulatory measures are appropriate. The European Parliament's conclusions are not yet final, but the UK position appears to be supported in that additional measures, other than monitoring the situation, are unnecessary.

It was acknowledged that mercury is a dangerous substance. However, it is still the safest restorative material in dentistry. Adverse incidents amount to less than 100, which indicates that it is very safe for these purposes. Mercury amalgam will continue to be used until a better material can be found.

8.3 Advanced Therapy Directive: CSD: 06/013

Mr Woodfield addressed the Committee. In late 2005 the European Commission published two sets of formal legislative proposals: i) European Regulation on advanced therapy medicinal products, including tissue engineering and ii) for an amending Directive on the Medical Devices Directive.

Two key issues have been identified. The first being that there could be regulatory gaps between medicines and devices regimes. The MHRA is of the view that there may be some products containing human or animal tissue or cells which could fall into regulatory gaps. Such products which do not meet the definition of a medicinal product and cannot currently be regulated as a device. Possible examples include human demineralised bone and vascular grafts with human collagen.

The second key issue is the hospital exemption. The proposed Regulation exempts products from the requirements of the Regulation where the product is both prepared in full and used in a hospital in accordance with a medical prescription for an individual patient. The UK's concern is that the wording of the proposed exemption is arbitrary, and that it might be better to link it to the characteristics of the activity rather than to specific institutional arrangements.

It is early days in negotiations and it is encouraging that there is a will to address the gaps. Action is in hand to establish an ad hoc advisory group to give advice to MHRA in relation to the European Commission's proposals.

It was recognized that this field could see the emergence of small innovative companies. However, the proposed regulatory environment could be very stifling for them, thus inhibiting innovation and development.

The Committee will monitor any findings of the ad hoc group.

8.4 **Medical Devices Directive: CSD: 06/014**

Dr Ludgate introduced this paper.

Since the Medical Devices Directive 93/42/EEC came into force, a number of issues have been identified. These issues are now being addressed in the revision of the Directive which is currently being undertaken.

Key issues include the following:

- definitions and boundaries, especially in relation to tissue engineered products
- clarifying the definition of a medical device to include the requirement as to “medical purpose”
- introducing a requirement that custom made devices be subject to the vigilance procedure
- emphasis on the need for clinical data and clarification of adverse events to be reported during clinical investigations
- a push for greater transparency

The amendments will mean that in the future more clinical data will be required. There should hopefully also be more clinical trials and better direction about which adverse incidents to report during trials.

A problem has been created by the introduction of the term “medical purpose”. Any suggestions from the Committee in relation to its definition would be appreciated.

9. **FEEDBACK AND UPDATE**

9.1 **Education programme: feedback from CD ROM and Medical Driving Licence pilot: CSD: 06/015**

Dr Clutton-Brock updated the CSD on the feedback received following the launch of the “Using Medical Devices Safely” educational programme and on progress to date with the Medical Device Driving Licence project.

Using Medical Devices Safely

Feedback has been received from Primary Care Trusts, Acute Care Trusts, Royal Colleges, the CSD and from individuals. The majority of feedback has been favourable.

There has been no specific criticism of the content of the programme. Negative feedback that has been received has been centred on production quality and the “soft” educational approach taken.

The MHRA proposes producing a second version of the programme covering the same areas of information but delivered using the tool proposed for the Medical Device Driving Licence with a new voice-over and images. The CSD unanimously supported the production of a second version.

It was suggested that consideration should be given to including primary and private care. A suggestion was also made to try to make the programme more fun without making it too difficult to produce.

The issuing of a certificate of completion was discussed. A certificate is important as it demonstrates competence and evidence of learning. It might encourage people to undertake the programme if a certificate is issued. Could a certificate be printed off upon successful completion of the programme?

Medical Device Driving Licence

Progress has been made on all 3 modules, and they will be delivered for review by the end of June 2006.

Discussions have taken place with the proposed Training Hub for Operative Technologies (THOTH). The potential for collaboration has been discussed and the MHRA has been invited to sit on the board.

The CSD endorsed this initiative.

10. ANY OTHER BUSINESS

Pete Philips (SMTL) noted as a point of information that testing with regard to inconnectors for intra-thecal was now complete, with none of the manufacturers passing all the tests. It seemed likely, however, that two of the manufacturers would go on to the second stage, hopefully with appropriate improvement in design.

11. DATE OF NEXT MEETING

6 July 2006.

PS 19.4.06-02