

**MINUTES OF THE COMMITTEE ON THE SAFETY OF DEVICES
MEETING: 22 MARCH 2007**

Members Attending:

CSD

Mr John Williams (Chair)
Mr Guy Alexander
Dr Steve Bennett Britton
Mr Christopher Earl
Mr Roger Evans
Dr Karen Facey
Mrs Christine Glover
Professor Ian Kimber
Professor Ian Learmonth
Dr John Perrins
Dr Charles Sears
Professor Irving Taylor
Dr Gary Thorpe
Dr John Turney
Dr Gordon Watkins

MHRA

Dr Susanne Ludgate
Mr Mike Peel
Mr Clive Bray
Professor Kent Woods
Mr Philip Grohmann
Dr Nevil Batra
Mr Stephen Lee
Mr David Grainger
Mr Brian Mansfield
Mr Tony Sant
Mrs Mel King
Mr Tom Clutton-Brock
Dr Elsie Damien
Mr Allan Hilderley
Mrs Fran Queen

NPSA

Dr Beverley Norris

Devolved Administrations (Observers)

Mr Andrew Wong (Scotland)
Dr Sara Davies (Scotland)
Mr Peter Phillips (SMTL, Welsh Assembly)

Industry (Observers)

Mr John Wilkinson, ABHI
Mr Mike Kreuzer, ABHI

1. WELCOME

1.1 The Chairman welcomed everyone to the Committee meeting.

2. APOLOGIES

2.1 Apologies were received from Dr Anna-Maria Belli, Miss Catherine Cairns, Dr Sheila Fisher, Dr Julie Kent, Mr Peter O'Donovan, Dr Sheila Peskett, Dr Geoffrey Ridgway, Professor David Sharpe, Mr Arvind Singh and Dr Carl Waldemann.

3. MINUTES OF LAST MEETING (07/001)

3.1 The minutes of the meeting of 30 November 2006 were agreed subject several editorial amendments. The minutes will be posted on the MHRA website.

4. MATTERS ARISING/ACTION POINTS

4.1 Orthopaedic screws: Mr Hilderley gave a presentation on reprocessing screws and plates used for osteosynthesis. He said that CSD had originally been presented with this issue at a meeting in 2002.

Screws and plates are predominantly used for treating fractures in orthopaedic and maxillo-facial surgery. Screws and plates that are used in patients are not re-used. However, during surgery a tray containing a variety of different sized screws and plates is provided for use, as the surgeon may not know which size screw or plate is needed until the fracture site is exposed. The screws and plates remaining in the tray that are not used during the operation are returned to the CSSD for sterilisation and re-use.

Although some surgeons were originally resistant to using individually wrapped sterile implants, believing this might lengthen the operating procedure, many now recognising the benefits, including removal of the risk of contamination.

In response to a recent Directive in Scotland, major manufacturers have assured hospitals that they will be able to provide individually wrapped sterile small implants by July 2007, and some are already doing so now. The Scottish Executive has required the mandatory use of such implants across NHS Scotland by 31 December 2007.

The ABHI representative confirmed that manufacturers were already producing individually wrapped sterile small implants. However, they thought that there was not a great demand for the larger ones to be similarly packed at present.

Members agreed that there was the benefit of removing contamination by using individually wrapped sterile small implants as opposed to having items decontaminated and sterilised by the CSSDs. However, there was a concern that using the individually wrapped items may be forced on others such as the dental profession when no evidence has been produced which might suggest that current practice was inappropriate. The current policy for mandatory use is only for NHS Scotland (the legality of this policy in Scotland has been called into question).

Members were also concerned about the cost of using individually wrapped sterile small implants, as the estimated cost in the MHRA's paper had suggested 0-100%. However, the ABHI said that the cost was likely to be very comparable to using current sterilisation procedures.

In conclusion, the committee felt that there was a valid concern that the requirement to use individually wrapped sterile small implants might extend to sectors other than hospitals. However, the use of individually wrapped sterile small implants would reduce the risk of contamination and the chairman agreed to write to BOA, BAOMS and Spinal Surgery Groups endorsing such a policy as it represents good clinical practice, yet the feeling of the committee was that this issue was one which should be led by the professionals involved.

- 4.2 Auto identification systems and patient safety: Dr Ludgate thanked the CSD for the comments made concerning auto identification at the previous meeting. These had been incorporated into the MHRA's "Coding for Success" report, which could be found on the MHRA website. DH fully supported coding standards and there is now a Working Party taking forward the recommendations in the report.

The ABHI welcomed the report and said that it was well balanced. They had joined the Health User Group, GSI.

- 4.3 Drug eluting stents: Dr Ludgate said that the Agency had had a meeting with NICE and the BCIS to discuss the issue of late stent thrombosis. The MHRA will be attending a workshop with the FDA in May to consider what further data needs to be generated with regard to the use of drug eluting stents for off label use. The advice on the MHRA website is still current but may change depending on the outcome of the workshop.

- 4.4 Single use medical devices - NPSA documents: Mr Bray said that a study had been commissioned by the NPSA four years ago on why single use medical devices were being re-used. The study was researched over a 24 month period, with a web based survey and interviews with clinical staff. There was a poor response rate to the survey.

Mr Bray thought that not a lot was learnt from the report. However, it highlighted that users did not understand the definition of single use. The report correctly identified labelling problems that the Agency will address with industry. Overall, the report did not adequately address the problems of re-use.

The ABHI said that the current revision of the Medical Devices Directive may allow for a better definition of what is a single use product. It may also disallow a manufacturer or distributor placing a single use product on the market in one Member State and marketing the same item as re-usable in another Member State. However, the revision to the Directive was still under negotiation.

Members considered that there was confusion about what was meant by single use, and whether an item could be used more than once on one patient, for example, stapling devices. The Chair thought that clarification was needed on the definition of single use and agreed to write to the Chairman of NPSA.

4.5 Mercury Directive: Dr Ludgate said that healthcare products are currently excluded from the Mercury Directive. However, this exclusion will be reconsidered in two year's time.

4.6 Mr Grainger reminded the committee that the European Commission has concluded a contract for an investigation into occupational exposure to electromagnetic fields for personnel working with and around medical magnetic resonance imaging equipment.

The Chair remarked that this was a serious issue that CSD and the Agency must be kept aware of. There is a serious risk that this ill considered Directive could interfere with medical practice, where no evidence of harm has been provided.

5. CONFLICT OF INTEREST: REMINDER

5.1 The Chairman informed Members of the need to declare conflicts of interest with any of the day's agenda items.

6. MAIN ITEMS

6.1 Vigilance Priorities Board: CSD: 07/003

Professor Woods gave a presentation on the role of the Vigilance Priorities Board (VPB). He began by saying that the Agency has three functions: facing industry, with assessments and authorisations; facing government, with policy; and facing patients, public and professions, with the vigilance and risk management of medicines and devices. The Agency has to consider how they communicate these functions.

The VPB was set up in May 2006 drawing together divisions concerned with vigilance for medicines, medical devices and blood. Its scope covers:

- reducing uncertainty on key risk/benefit issues;
- understanding stakeholder needs in relation to risk:benefit issues;
- monitoring impact of regulatory action;
- strategy development;
- horizon-scanning/new vigilance methodologies;
- look for and build upon synergies

The VPB has met several times to consider issue such as metal-on-metal hip implants, replacement for SABS, and Hepatitis-B transmission in care homes. Its forward programme includes looking at areas such as the impact of Agency actions, communications (e.g. synergies between Medical Devices Liaison Officer and pharmacists), and specific safety themes (e.g. Implantable Cardioverter Defibrillators). Professor Woods invited the CSD for suggestions of other areas for consideration.

6.2 a) Working with the Health Service: CSD: 07/004, CD ROM

Mr Grohmann informed the committee that the MHRA published 73 Medical Device Alerts in 2006. It was important to get the information right and also to get it to the right people. There had also been 6 Device Bulletins, 9 One Liners and 6 posters and leaflets produced.

More and more counterfeit products are finding their way onto the market, and there is a need to inform consumers. It is sometimes very difficult to distinguish between counterfeit items and the genuine article. Communication of these issues is a challenge that the MHRA is trying to address.

The MHRA has worked with other organisations to produce some of the posters. A poster on monitoring blood pressure was produced in association with PULSE. This has received positive feedback. The MHRA produce posters for different target audiences, for example, users and the healthcare industry.

The MHRA use targeted letters when they know who is responsible for a suspect medical device.

b) Comment from a newcomer:

Dr Batra had recently joined the Agency. He gave a presentation to the Committee on some changes that he felt could be made to MHRA publications for ease of reading. He proposed:

- i. a proposed re-design of MDA (2007/17) as an example, where he said coloured pictures and a heading (that includes the manufacturer, model, action being taken and clinical effect) are required on the front page so the recipient can see at a glance what the Alert is all about;
- ii. four variations of an orthopaedic poster with different messages, styles and colour schemes for discussion; and
- iii a new journalistic style publication “*Safety Solutions*” which, could be distributed by e-mail only. There needed to be a discussion, however, on whether such a document was needed to fill a publication gap.

Comments from the Committee

Medical Device Alerts:

Regarding MDAs, one member stated that the re-designed MDA in the “F” format was clearer for GPs since that is the way they scan/read documents. Some members liked the more colourful design. However others indicated that Alerts are copied within Trusts and coloured leaflets do not photocopy well. Some members thought that pictures were helpful; others thought them unnecessary. It was also pointed out that we needed to be careful about using pictures where generic messages were being given. A link to websites for further information was felt by some to be helpful.

Orthopaedic Poster:

There was some discussion indicating that the new design was more eye-catching, with the previous poster both dull and inappropriate.

New Proposed Publication “*Safety Solutions*”:

The Committee did not comment on the need for the “*Safety Solutions*” publication. However, one member mentioned that not all recipients have e-mail so it would incur distribution costs. Further discussion within the Communications Group of the CSD might be helpful.

Other issues/suggestions:

Other issues/suggestions raised by members of the CSD included:

- i. making the font larger on information MHRA produced so users and carers can read them more easily; and adding the MHRA address and telephone number for further information, as well as a website address, since not everyone has access to the internet and some of the publications only listed a website address;

- ii. consider distributing Alerts to medical schools since they are of use to medical students; and
- iii. alerts should be included in journals and medical newspapers (eg Hospital Doctor) as flyers.

Members asked if there was a way of auditing Medical Device Alerts and how they are working. The MHRA members reminded the CSD that there was feedback from recipients on alerts and the SABS system provided basic statistics on receipt/action taken by NHS Trusts and the social care sector.

The Chair concluded that a further communication group might need to be set up, including members of the CSD, to address the comments made and consider possible new design and format.

DEVICE RELATED ADVERSE INCIDENTS

6.3 MHRA has been working with doctors.net on an initiative to try to involve doctors more. Where do we go from here? CSD: 07/009

Dr Ludgate said that the Agency had been working with doctors.net to try to persuade doctors to report more adverse medical device incidents.

Dr Ringrose from doctors.net gave a presentation on the results of their pilot study. Doctors.net is an online daily conference available to over 30,000 doctors. They hoped to encourage doctors to report more adverse incidents through reading items on this forum. Their findings were that currently, only 10% of incidents are reported to the MHRA and yet 51% reported to the Trusts. They needed to change doctors' behaviour with regard to reporting and facilitate clinical engagement.

Dr Ringrose said that their recommendations were to build on a successful pilot and use a targeted approach to doctors. To close the loop there should be an ongoing programme to inform relevant doctors of recent reports and actions taken, which will be a strong driver to increase reporting.

ABHI commented that many adverse incidents are caused by user misuse, which distorts the number of reports truly attributed to product malfunction.

Members commented that doctors consider that they have more important work to do than report adverse incidents. NHS operators are worried that if they report a malfunction, then they will be blamed for causing it, even if there is a genuine problem. It was noted that professionals frequently work as members of a team so that it may not be the professional involved who actually reports the incident.

Members asked if MHRA could informally identify adverse incidents from the chat-room on doctors.net.

Doctors.net was felt to be a useful tool for reaching doctors, but members asked how could the Agency target nurses and others?

Members commented that they did not receive feedback when they reported an incident to the MHRA. They thought that their report could be circulated to certain groups to see if they had encountered similar problems.

Members asked how the medicines side of the Agency dealt with adverse drug reactions using the Yellow Card Scheme. They had noticed that monthly statistics on most reported drugs are published on the website. Perhaps devices could use some of their ideas.

6.4 **Problems of communicating adverse event advice with a non professional audience:**

a) **Devices purchased over the counter: CSD: 07/007**

Mrs King gave a presentation on the Agency's strategy of dealing with adverse event advice for products purchased over the counter. In recent years, there has been an increase in quantity of equipment supplied and the range of equipment has become more diverse. In addition to the diverse numbers of healthcare professionals and paramedics using devices, many more members of the public now had direct access to them.

The range and availability of products to members of the public is as diverse as blood pressure monitors to powered wheelchairs. Many devices are now stocked in catalogue stores such as Argos. However, when problems occur with these devices, it is difficult to reach the end user. Manufacturers may send out recall notices to stores, but how will they reach the end user? A possible way forward would be to build on the excellent working relationships the Agency has with trade associations. Also, there could be increased liaison with trading standards and the FDA. MHRA could also approach the National Pharmacy Association, with a view to disseminating information through community pharmacists.

Members suggested that the purchasers of some devices might be identified via the details held from supermarket loyalty cards. Mr Bray said that this had been done previously by one company, but the Agency could not have direct access to these databases, as there may be data protection issues.

7. UPDATES

7.1 Problems associated with diathermy use: CSD: 07/011

Mrs King provided an update on what has occurred with the Agency's work with diathermy manufacturers over the last 12 months.

Recommendations had been made that there is a need for manufacturers to provide hospitals with information on power settings, as sometimes surgeons found it difficult to know what output was being delivered.

The MHRA held a meeting with the four largest diathermy manufacturers in March 2006, where progress had been made. The outcome of that meeting was that look-up tables to use with equipment had been considered. Two companies, Eschmann and Valleylab have subsequently produced look-up tables. Conmed hope to issue their template later this year and ERBE will review the issue during the year. However, ERBE have produced extensive information in their user manual.

Electrosurgery is used by most surgeons, so they should have equipment that they can use easily use without the use of an aide memoire. It was disappointing that the four manufacturers could not use the same dial settings on their equipment. It would take a long time to go down the route of standardisation and this option had addressed the problem more quickly.

8. MAIN ITEMS continued

8.1 Problems of communicating adverse event advice with a non professional audience:

b) counterfeit products: CSD: 07/006

Mr Lee stated that there was an increase in the number of reports on counterfeit products to MHRA in the last couple of years, and many, such as condoms, are aimed at the consumer market.

On receiving a report of a suspected counterfeit medical device, the MHRA has to decide on the level of action to take. A risk assessment is undertaken, considering factors such as:

- the possible risk to patients;
- whether the product is confirmed counterfeit;
- whether the product is available to UK consumers/retailers;
- how much product is available on the UK market;
- whether the product is easily identifiable as counterfeit;
- whether legal enforcement action is possible.

The MHRA has taken action to date against counterfeit products by issuing Medical Devices Alerts, issuing press releases, placing a note on the MHRA website, and by notifying other Competent Authorities. Additionally, some manufacturers of genuine medical devices have tried to highlight the problem when their products have been illegally copied.

Mr Lee asked the Committee for their opinion on how the MHRA should decide what action to take; what else do they need to do to get the message across; and should the MHRA use a dedicated web-brief.

One member noted that what MHRA is doing seems to be effective and suggested that an audit may be useful.

Members highlighted the possible problem of buying counterfeit products over the internet, which may or may not originate in the UK. The ABHI were concerned that the UK was becoming a distribution hub for counterfeit products. They asked if there was any obligation on Notified Bodies to report suspected counterfeit products if they comply with the regulation but have not been through the appropriate conformity assessment procedures? No such obligation exists.

Members thought that a dedicated web page was a good idea. They asked if the MHRA had links with the Consumers Association? Dr Ludgate replied that they had previously tried to engage the Consumers Association, with little success. However, they may try again.

Members liked the leaflet on faulty medical equipment, and recommended that this and similar leaflets should be sent to doctors surgeries.

8.2 **The importance of understanding electrical circuits and electrical supplies in hospital: CSD: 07/008**

Mr Mansfield gave a presentation on safety issues linked to the standard of electrical installation and wiring of medical devices in hospitals. He said that the MHRA had received a variety of incident reports from radiology departments. The most common reason for electric shock from medical equipment was from inadequate earthing. An earth reference bar should be found in every installation. However, there were many unsafe installations in hospitals and the MHRA needed to get the message out that equipment should be properly earthed.

Other problems included an insufficient number of sockets, use of extension leads, and use of equipment with continental plugs through unsuitable “shaver” adaptors. Refurbished radiology rooms need their wiring upgraded whenever new equipment is installed.

The MHRA has issued MEIGaN guidance on their website, which they would like to see used with all new medical installations.

The Chair said that they had previously presented this issue to NHS Estates. In the light of this continuing evidence of poor standards, the Committee now needs to discuss how best to take this forward. Members asked if there was a relevant magazine in which this matter could be highlighted? They thought that the MHRA should be targeting policy people to ensure that electrical safety is addressed when upgrading electrical installations. Members asked if the MHRA could work with the HSE to take this forward. Unfortunately, HSE will only get involved once an accident has occurred.

Members discussed the possible reasons that sub-standard wiring may occur in hospitals and suggested that we look into ways of ensuring that work is carried out to the required standard. It was suggested that contractors who are familiar with domestic and commercial standards may not be aware of the need to apply higher standards when working in a medical location. Members thought that maybe there should be a legislative change resulting in NHS Estates having to conform to appropriate electrical standards. IEE Regulations Part P should already apply to private dental practices but MEIGaN should also be applied. The Chairman said that if it was a PFI, there needed to be a check to see that all of the relevant standards are applied. Members thought that Ministers should be informed of this serious issue. The Chairman agreed to contact relevant individuals.

8.3 **Vigilance guidelines: how will this impinge on clinical practice: CSD: 07/010**

Mr Sant gave a presentation on the updating of the Vigilance MEDDEV guidance document. The original guidance was difficult to navigate, with little or no definitions. Reporting exemptions are being misapplied, and maximum timescales are frequently used. There are no means of addressing user error reporting. There is confusion about what constitutes a reportable recall action, and product recalls are not always communicated to all who need to be aware. Some manufacturers' advisory notices serve as advertisements rather than important safety communications. There was also a lack of clarity on the role of the co-ordinating Competent Authority.

The new updated guidance which sought to address the problems will be available on the European Commission's website in a couple of weeks' time. It will also contain new chapters on Notified Bodies and users. Mr Sant thought that this was a much improved guidance document.

Mr Sant asked the Committee if there was anything the MHRA should be doing to encourage the necessary engagement between clinicians involved with incidents and manufacturers. Members said that if a

clinician had a problem with a medical device, they would report the problem to their procurement department. They presumed that the procurement department took it up with the manufacturer, but heard no more about it.

9. UPDATES continued

9.1 Medical Device Education Programme: CSD: 07/012

Dr. Clutton-Brock updated the Committee on the medical device education programme. Progress had been made and the MHRA was targeting three areas, in the first instance, to produce modular programmes. The MHRA had completed the electrosurgery draft and the programmes on operating tables and anaesthesia workstations were approaching completion. The MHRA will put these modules on a Medical Devices education section of the MHRA website, which would be open to professional users, but not the general public.

The educational material that the MHRA has produced is value for money and is flexible, so can be easily updated. Dr. Clutton-Brock showed examples of one of the modules that will go on the website containing 43 animated slide presentations with a voice-over. CSD commended Dr Clutton-Brock on this product.

9.2 Expert Advisory Group on Metal Debris from Hip Implants CSD: 07/013

Mrs Christine Glover, Chair of the Expert Advisory Group on Metal Debris from Hip Implants, informed members that the EAG last met in January. The problem was more difficult than originally envisaged, as the right research was not available.

Dr Damien updated the Committee on the work of the EAG. There have been over 60,000 resurfacing hip procedures in total in the UK. Metal wear debris generated from metal hips may produce genetic changes which might result in genotoxicity. The aims of the EAG are to assess the clinical significance of the reported genotoxic effects; to put these into a risk-benefit context; and to provide appropriate advice to both clinicians and patients.

The EAG's first meeting was held in October 2006. At that meeting, the EAG considered the available evidence on both possible and potential risks, and clinically perceived benefits of metal hips. It concluded that the biological hazards are not associated with clinical effect, and that there was no evidence of clinical manifestation of the genotoxic effect.

At the EAG's second meeting in January 2007, the Risk-Benefit document drafted by the MHRA was discussed. The meeting concluded that no toxicity threshold level has been established for the toxic effects of metal ions or particles, different studies are not comparable because of incomparable endpoints, and that there was not enough information currently available.

Members thought that this was an area that invited coordinated research. The EAG needed to identify which issues can be addressed by research, and what can be standardised, both nationally and internationally.

10. ANY OTHER BUSINESS

None

11. DATES OF NEXT MEETING

5 July 2007