

COMMITTEE ON THE SAFETY OF DEVICES

THURSDAY 9 JULY, 2009

10.30am – 3.45pm

ROOMS CR1/CR2

19 FLOOR, MARKET TOWERS, 1 NINE ELMS LANE, LONDON SW8 5NQ

<u>Members Attending</u>	<u>MHRA</u>
Dr John Perrins (Chairman)	Dr Susanne Ludgate (Secretariat)
Dr Steve Bennett Britton	Mr Clive Bray
Dr Graham Brown	Ms Boyode Adisa
Mr Bernard Chang	Dr Christopher Brittain
Professor Matthew Cooke	Dr Tom Clutton-Brock
Mr Geoffrey Crawford	Mr Peter Commins (AM Only)
Professor Ellis Downes	Ms Melissa Coutinho (AM Only)
Mr Christopher Earl	Ms Valerie Field
Dr Michael Gammage	Mr Stephen Lam (AM Only)
Mrs Christine Glover	Mr Michael Lawrence (AM Only)
Professor Stephen Halloran	Mr Alan Lynch
Mrs Rosalind Ham	Dr Louise Mulroy
Professor Simon Kay	Mr Michael Peel
Professor Ian Kimber (AM Only)	Ms Rosalind Polley
Dr Richard McWilliams	Dr Roopa Prabhakar
Dr Sheila Peskett	Mrs Hazel Randall
Dr Paul Rylance	Mr Tony Sant
Dr Michael Simmons	Mr Richard Gutowski
Dr Peter Thornton	Mr Fred Huckle
<u>Devolved Administration</u>	<u>Industry</u>
Dr Martin Donnelly	Mike Kreuzer
Mr Peter Philips	
Mr Andrew Wong	
	<u>Medtronic</u>
<u>Apologies</u>	
	Dr Susan Alpert
Mr Guy Alexander	Mr Tim Samsel
Dr Karen Facey	Ms Luann Pandy
Dr Sheila Fisher	Mr David Dunham
Professor Ian Learmonth	
Mr Irvine Taylor	
Dr Carl Waldman	

1. WELCOME

The Chairman welcomed the members the meeting which, for many of them, would be their first.

2. APOLOGIES

Apologies were received from **Professor Ian Learmouth, Drs Karen Facey, Dr Sheila Fisher and Carl Waldman, Mr Guy Alexander and Mr Irvine Taylor**

3. INTRODUCTION BY CHAIRMAN, DR JOHN PERRINS

The Chairman first wished to officially thanks his predecessor, Mr John Williams, for his work since the creation of the Committee.

He stated that, while he would be making a presentation later about the future of the CSD, he wished to inform the membership that, because of the importance of its work, members would be expected to attend at least two of the three meetings held each year. If they were unable to do this, then, depending upon circumstances, they may be asked to resign.

**4. INTRODUCTION TO MHRA BY MR PETER COMMINS,
DIRECTOR OF OPERATIONS AND FINANCE MHRA**

Mr Commins first wished to pass on the apologies of Professor Kent Woods, Chief Executive of the MHRA, due to ill health.

After welcoming the Committee, and its new Chairman, he stressed the importance of the CSD to the work of the MHRA in its commitment to the protection of public health. He hoped to see a raising of the profile of devices in general and informed the meeting that the former CSD Chairman, Mr John Williams, had been appointed as a non-executive director of the Agency Board.

He finally stated that the independence of the CSD was vital to the confidence that the NHS, the general public and all our other stakeholders could place in all information given on devices.

5. INTRODUCTION OF MEMBERS, MHRA PERSONNEL AND OBSERVERS

The Chairman then called upon all present to briefly introduce themselves.

6. MINUTES OF LAST MEETING

The minutes of the last meeting were approved for publication.

7. MATTERS ARISING/ACTION POINTS (09/012)

ELECTRONIC MEDICAL DEVICE ALERTS (EDMA)

Mr Clive Bray, Director of Device Technology and Safety, MHRA

Mr Bray reported that the system had gone “live” on the 1 April. After some initial teething problems, there had been a high level of positive feedback from our stakeholders in general, including many former Committee Members.

MEDICAL DEVICE TECHNOLOGY FORUM

Dr Christopher Brittain, Senior Medical Officer - Devices Clinical, MHRA

Dr Brittain gave the Committee a brief background to this twice-yearly, forum. He stated that this forum had been set up to educate the MHRA on new and emerging regulatory and safety concerns regarding medical devices and their associated technologies. The two meetings, held so far, had covered Human Tissue Engineering and Novel Technology Medical Devices. The next event was due to cover the subject of Registries.

He encouraged all members to actively participate in the forum, including the submission of suggestions to the Topic Selection Panel.

METAL ON METAL SOFT TISSUE NECROSIS

Dr Susanne Ludgate, Director of Devices Clinical, MHRA

Dr Ludgate gave the Committee a brief background on this issue. Following the return of questionnaires, to the National Joint Registry (NJR), from relevant clinicians, the following questions had been raised:

- (a) Are metal-on-metal hip replacements performing better or worse than other hip replacements?
- (b) Is there an association between soft tissue reactions and any particular type of metal hip implant?
- (c) Is there an association with any other patient characteristic, eg, sex or age?

Dr Ludgate stated that there would be a further meeting between the MHRA, the British Orthopaedic Association (BOA) and the NJR in September.

DIALYSIS HAEMOLYSIS ISSUES

Ms Valerie Field, Unit Manager – Imaging and Acute Care, MHRA

Ms Field gave the Committee a brief background on this issue. It related to problems associated with patients’ haemolysing during and after their dialysis sessions. These involved 11 patients, on four different sites all in Northern Ireland, between September and December 2008. No common factors or causes had been found.

Since the last meeting of the Committee, two further cases had been reported, both involving “kinking” in the lines. These two incidents may indicate that further training in usage may be appropriate. No further reports had been received in the last two weeks. Investigations are ongoing.

Dr Paul Rylance (CSD) stated that there may be factors regarding the local water supply, and that guidelines on water standards may need to be issued.

When asked about similar incidents in the US, Ms Field stated that the FDA had in the past seen clusters of haemolysis but had also been unable to establish common factors. Water supply contamination from extremely heavy rainfall had been considered.

Dr Michael Simmons (CSD) stated that there had been a relevant incident in Wales, and that he had asked the relevant Trust for full details. Ms Field and Dr Ludgate confirmed that this had not been reported to the Agency.

The Chairman remarked that this was “depressingly familiar”. He asked all members to promote user reporting in their respective areas as under reporting “devalued the functions of the Agency”.

MEDICAL DEVICE TRAINING CENTRES

Mrs Christine Glover (CSD)

Mrs Glover reported that, as he had stated at the previous meeting, the then Committee Chairman, Mr John Williams, had written to the Chief Medical Officer, Sir Liam Donaldson, on this issue. Mr Williams had not been happy with the “somewhat dismissive” reply received.

Dr Perrins stated that he would be addressing this issue in his presentation to the meeting.

8. CONFLICT OF INTEREST: REMINDER

The Chairman reminded members of the need to declare personal specific and non-personal specific and non-personal specific and non-personal non-specific interests in the agenda items. No interests were declared.

9. MAIN ITEMS

i How Devices are Regulated Mr Richard Gutowski, European and Devices Section Head, Policy Division, MHRA

Mr Gutowski made a presentation to the meeting which he intended as a “short snap-shot” of the past, present and future of device regulation.

After reminding the meeting that, at any given time, there were between 80 and 100 thousand in use, he stated that, after lobbying by Industry, the Medical Devices Regulations (SI 2002 No 618) had been brought in. It incorporated a number of existing EC Directives, the main three being:

- Active Implantable Medical Devices
- Medical Devices
- In-Vitro Medical Devices

He explained that the MHRA (the Agency), reporting to the Secretary of State, was the Competent Authority (CA) for the UK. While it performed a mainly post marketing function, there were occasions, such as Clinical Trial Notification, where it had a pre-marketing role.

He explained the role of the Notified Bodies, of which 60 exist throughout Europe and 8 in the UK. These were “Third Party Independent Certification Organisations”, whose function was to assess manufacturers (of higher risk devices) and issue EC Certificates of Conformity. One role of the Agency was to designate and audit these bodies and, on one occasion, a body had been de-notified for failure to meet acceptable standards.

The requirements of manufacturers depended upon the risk level associated with any given device – the higher the risk, the higher the degree of compliance necessary.

There would be occasions when the Agency could authorise the use of non-CE marked devices. This could be in the case of a single named patient where there was no CE marked alternative or the non-CE product offered a reduced morbidity/mortality risk. Another case would be the need to augment existing devices due to shortages caused by a pandemic.

Coming to possible future developments; these would include revision of the Device Directives, a “fundamental review” of the In-Vitro Medical Devices Directive, initiatives on counterfeit devices and the reprocessing of devices, Advanced Therapy regulations, the implementation of the Hampton Report and the introduction of Macrory Sanctions, and the reclassification of devices containing viable human tissue as Medicines for regulatory purposes.

In response to questions from the Committee, Mr Gutowski explained the following:

- Manufacturers were obliged to report not only fatal, or potentially fatal, events, but also any systematic recalls or failures of standards.
- Methods of unique device identification were being increasingly used in the USA, although these were primarily for use in anti-counterfeiting.
- A CA has the power, under the Consumer Protection Act, to remove a CE marking. In 95% of cases however, agreement was reached with the manufacturer.

- Mandatory user reporting had been tried in various countries, including France and Germany. It had been found not to work as in practice it was unenforceable.
- If a product came under the definition of a Medical Device, it made no difference if it was not being sold as such. It still came under the same regulations.
- If a device was being made purely for self-use, it would not come under the remit of the regulations. Once a product was being marketed in any way however, it would.
- In all cases, where a manufacturer had self-certified a CE Marking, it was the responsibility of the Notified Body to review all clinical data.
- In cases where concerns were raised over products coming into the UK from other European states, the Agency would contact the relevant CA who would be obliged to investigate.

The Chairman thanked Mr Gutowski for his presentation.

ii POST MARKET SURVEILLANCE (PMS) AND VIGILANCE IN THE MEDICAL DEVICE DIRECTIVES

Mr Clive Bray

Mr Bray began by explaining that the importance of adverse incident investigation in protecting the public's health. He stated that, while a voluntary reporting system had been in place since 1965, the mandatory system for manufacturers had been introduced as a requirement of the EU Medical Device Directives (MDDs).

The manufacturer was required to institute and keep up to date a PMS system that would allow for both experience gained from the use of the device to be reviewed and for necessary corrective action to be taken. There was also a duty to report all serious events and field safety corrective actions (recalls) to the CA.

Under the same directives, the CA of each Member State must: Record and evaluate the incidents centrally, inform the manufacturers of any adverse incident reports received from user, and inform the Commission and other Member States of any measures taken.

Mr Bray then outlined the guidance on PMS and Medical Device Vigilance. He presented a number of slides showing different statements. He asked the members to decide whether the each statement was a legal requirement, a recommendation or not mentioned. This illustrated the complexity of the Directives.

He then explained how Agency managed vigilance reports, highlighting the data management systems that were "second to none in Europe".

He finally informed the meeting that there had been 8,902 reports received in 2008, resulting in the following actions:

- 88 medical device alerts issued
- 96 notifications to other EU member states
- 568 manufacturer field safety corrective actions
- 250 other manufacturer field actions
- 363 cases requiring provision for advice on safer use or improved staff training
- 822 manufacturer undertakings to improve designs, manufacturing processes and quality systems

The Chairman thanked Mr Bray for his presentation.

iiia PMS - ASSISTIVE TECHNOLOGY (A CASE STUDY)
Mr Alan Lynch,
Head of the Centre for Assistive Technology, MHRA

Mr Lynch began by listing the different types of Assistive Technology Device:

- Mobility aids
- Environmental controls
- Communication and hearing aids
- Posture and pressure management
- Moving and handling systems
- Devices for the alleviation of or compensation for a disability

While the use of these devices was increasing, there was often no “trained healthcare professional” directly involved in the prescription, use or maintenance of these products.

He stated that the Agency received around 1,500 adverse incident reports each year about these devices, although less than 10% of them came from the manufacturer. During 2008, 30 reports had concerned fatalities.

146 of these reports, including 5 fatalities, concerned hoist and slings. His presentation would detail one such recent event to illustrate the issues involved.

An elderly female patient in a nursing home was being transferred, using a hoist and textile sling, from a chair to her bed. During the transfer, one of the webbing straps gave way, the patient fell to the floor and, subsequently, died from cardiac failure.

The incident was reported to the Agency by the Coroner’s Office, but not by either the manufacturer or the nursing home.

Those involved in the subsequent investigation were:

- The nursing home staff
- The Health and Safety Executive*

- The Coroner's Office*
- The Manufacturer
- The Agency Devices Compliance Unit

* Over the past five years, there has been a considerable increase in cases where Coroners, the HSE and the Police have become involved.

Findings:

- Sling was 2 years old.
- Safety-critical stitching that secures the webbing strap to the sling body was missing
- No maintenance or pre-use checks were carried out on the sling at the nursing home
- MHRA records show no evidence of a widespread problem at this time
- 30,000+ slings from model range sold since 1998
- Manufacturer was unable to prove that this was an isolated manufacturing incident (lack of manufacturing specification and control)
- The manufacturer's instructions for use provided insufficient guidance on the inspection of slings for faults, damage, wear etc and how to clean the slings between use

Outcomes – Short-term:

- Manufacturer has improved internal control systems.
- Revised instructions for use produced by manufacturer including inspection and cleaning but poor traceability to all users.
- Medical Device Alert (MDA/2009/041) issued 22 June 2009 to highlight need to obtain and adhere to new IFU.
- Improved systems & procedures in the nursing home enforced by HSE.

Outcomes – Long-term:

- Potential lack of cleaning and inspection detail across the industry raised with BHTA.
- New BHTA decontamination interest group established.
- Shortcomings identified in the European harmonised standard for hoists and slings (contrast colour stitching, testing etc).

- Shortcomings in the Harmonised Standard raised with the Devices compliance unit and BSI to instigate revision.
- Improved understanding and working relationship with HSE in the North West.
- Findings fed into the drafts of the guidance document (Device Bulletin) on hoist and slings safe use presently underway in AT.

The Chairman thanked Mr Lynch for his presentation.

iii COMMUNICATION WITH HEALTHCARE PROFESSIONALS **Dr Christopher Brittain**

Dr Brittain began by highlighting the confusion created by the existence of so many healthcare-focused public and private organisations, and thus the difficulty for MHRA in getting its information to those that need it. He explained what the Agency was already doing to publicise information, using both paper and electronic publications. Increasingly, however, the problem of “information overload” was affecting the NHS, as it was all walks of life

The Agency was addressing this problem by targeting specific information to specific professionals. While it had to be remembered that within each specialist area there were a large number of sub-specialities (The British Orthopaedic Association and the British Cardiovascular Society had 35 between them), it had already created a number of dedicated web pages:

- Ophthalmology;
- Orthopaedics;
- Obstetrics and Gynaecology;
- Radiology;
- Cardiology;
- Pathology;
- Pharmacy;
- Theatre Practitioners.

Further pages were being planned.

Other methods included holding stands at conferences, giving talks at society meetings and using the network of Medical Device Liaison Officers. Jointly with NICE, the Agency had held a conference for junior doctors. Disappointingly, only around 1% of them were aware of any device publications.

The vast majority of professionals, who were familiar with the Agency, had given very positive feedback about MHRA information - citing the perceived quality of the information given out – and returned to it time and time again as a source of information. The challenge of raising awareness of who the Agency is, and what it does, was an ongoing concern. Future developments would include:

- Further joint conferences with NICE and other agencies

- Further stands at relevant conferences
- NHS Evidence accreditation

The Chairman thanked Dr Brittain for his presentation.

iv AUDIT OF CLINICAL INVESTIGATION SYSTEM Dr Susanne Ludgate

Dr Ludgate began by explaining the background to the audit. It had been conceived to address concerns by industry that the Agency, as CA for the UK, was “acting more stringently” than other CAs when it came to raising grounds for objection. Given the acceptance, by industry, of the independence of the CSD, it had been decided that an audit would be carried out, by members of the Committee, of a number of, randomly selected, clinical investigation notifications, representing between 5 and 10% of the total, in any given year.

The aims of the audit are to assess:

- concordance with the conclusions of the CA;
- concordance with the grounds for objections raised (if relevant);
- clarity of communication with the manufacturer;
- appropriateness and standards of both chosen internal and external assessors;
- adherence to written protocols and procedures.

The twelve members (four for each of the three audits of 2008 investigations), who had been selected, would be working with the Chairman and meet via teleconferences.

10. COMMITTEE ON THE SAFETY OF DEVICES (CSD): A VISION OF THE FUTURE Dr John Perrins

Dr Perrins began by giving a resume of the functions of the CSD. It had been set up, in April 2001, to advise Ministers and complement the work of the Medical Devices Agency. The Committee was to take a strategic view of initiatives to make devices and their use safer and more effective, offer advice on the development of device related policies, advise on the Agency’s communication with the Health Service and be part of the Quality Assurance System. These functions were to continue on the merger, in 2005, of the MDA with the Medicines Control Agency to form the present MHRA.

Although the CSD had been set up as an independent body, and not “a rubber stamp” for the views of the Agency, the Committee was entirely reliant on the Agency for its administration and infrastructure. The members may wish to consider whether, and how, the Committee might demonstrate that independence.

Focusing on the existing functions of the Committee, he highlighted the following areas:

- provide specialist/clinical support and perspectives to MHRA team;
- audit Pre-clinical Investigation submissions;
- resolve or appeal conflicts with manufacturers;
- consider specific issues raised by MHRA Devices;
- participate in Communication/strategy group;
- formation of ad hoc advisory groups.

There were areas that were already working well; acting as an appeal process as an alternative to a Judicial Review, the ongoing improvement in communication and the audit of clinical investigation submissions, were all positive.

There were areas, however, that he felt could be strengthened; the employment of tripartite meetings (CSD, MHRA and Industry), in both Regulation and regulatory enforcement, and the use of focus group audits for technology appraisals were but two.

Looking to the future, he was seeking a deeper involvement of the CSD in Devices processes in several areas. These being:

- Medical Device Alerts (MDA) - email relevant draft alerts to CSD prior to final issue for comments/revision*.
- Consultation with CSD at earlier stages of MDA development.
- Feedback to CSD about issues where no action was taken or needed.
- Chair to participate in the Technology Management Group.

*Draft alerts, relevant to their specialist areas, would be emailed to expert members, and to all lay members. In addition, any member could receive all such draft alerts if they so wished.

As for raising the profile of the Committee: meetings had already been held with the General Medical Council (GMC) to promote the inclusion of devices in their "Fitness to Practice" agenda. Similar meetings were now being planned with The Nursing and Midwifery Council. Was there a case for pursuing this with other professional regulators and for direct communication with students/trainees? There were plans for increasing cooperation with NICE, particularly in the New Interventional procedures group.

Further questions for the Committee were: is or should the MHRA promote the CSD and how should the CSD interact with industry?

There was a strong feeling that, since the merger of Devices and Medicines into one Agency, Devices had been "submerged" by Medicines! To help address this, the Chairman had been invited to attend a meeting of the Commission on Human Medicines (CHM), while the CHM Chair would be invited to a meeting of the CSD. A

specific aim would be the creation of an integrated reporting system, for both devices and medicines, based around existing electronic systems for adverse events/reactions. There still seemed to be some way to go, however, in convincing the Medicines side of the Agency of the importance of Devices.

There were, of course, constraints on what the Committee could and could not do. While, however, the Committee were bound by issues of courtesy, common sense, and commercial confidentiality, it did have a duty to ask questions, and right to expect answers, about issues where the Agency were debarred by the Device Directives. The afternoon session would be a case in point.

Coming to the kinds of interaction that the CSD needed to promote, or at least consider, in order to return focus to the “Patient Agenda”, the Chairman suggested:

- neutral forum for manufacturers to discuss quasi regulatory issues;
- inform users and purchasers of the functions of the CSD;
- do we need to talk to other regulators? Eg FDA;
- promote contact between other agencies particularly NPSA;
- lobby DOH directly?
- CSD may need to promote or arrange workshops or meetings.

As for the “Public Face” of the Committee; Dr Perrins asked whether the Committee meetings should be formally public meetings, as were those of NICE. He stated that he had already set up a separate email address for the CSD Chairman. He asked whether it may be desirable for the Committee to have its own web site, distinct from that of the Agency, or run a Devices Blog or something similar. Members might also wish to consider whether should engage directly with the media. He certainly felt that there should be a CSD Annual Report, which would be widely distributed, and more direct contact with industry.

He believed that, at present, the Committee was being merely reactive to an Agency driven agenda and issues. In order to perform a more proactive role, he asked the Committee to consider a number of possibilities:

- CSD members to analyse their individual specialist areas – suggest topics/present to CSD;
- direct requests from Industry;
- network with other primary agencies and/or DOH;
- network with private providers;
- where is the patient/user in the largely secretive/confidential world of device regulation?

He finally outlined a number aims that the Committee should set for itself:

- the CSD is a large committee to use it effectively requires more activity outside of CSD meetings;
- the CSD must be “alive” between meetings for members;
- more contact with MHRA and individual members is required;
- members must actively promote the activities functions and responsibilities of the CSD;

- use the independence of the CSD to its full potential particularly to consider issues outside of the regulatory legal environment.

He believed that, when the present terms of office expired in 2013, these actions would enable the Committee to look back and know that it had made a valuable, and valued, contribution to the protection of public health. He thanked the Committee for their attention and hoped that over the next days and weeks members would feedback on all the issues raised.

The meeting adjourned for lunch at 1.05pm and resumed, as a closed session, at 1.45pm

11. ANY OTHER BUSINESS

There was no other business

The meeting ended at 3.45pm

The next meeting will take place at **10.30am on Thursday 5 November, 2009**