

COMMITTEE ON THE SAFETY OF DEVICES

THURSDAY 5 NOVEMBER, 2009

10.30 – 15.50

MHRA, ROOMS CR1/CR2

19 Floor, Market Towers, 1 Nine Elms Lane
London SW8 5NQ

<u>CSD members</u>	<u>MHRA</u>
Dr John Perrins (Chairman)	Dr Susanne Ludgate (Secretariat)
Mr Guy Alexander	Mr Clive Bray
Dr Steve Bennett-Britton	Sir Professor Alasdair Breckenridge (am only)
Dr Graham Brown	Dr Christopher Brittain
Mr Bernard Chang	Dr Tom Clutton-Brock
Mr Geoffrey Crawford	Ms Melissa Coutinho (am only)
Professor Ellis Downes	Ms Valerie Field
Mr Chris Earl	Mr Jonathan Plumb
Dr Karen Facey	Mr Michael Peel
Dr Sheila Fisher	Mr Philip Grohmann
Mrs Christine Glover	Mr Tony Sant
Professor Stephen Halloran	Mr Steve Owen
Mrs Rosalind Ham	Mr Richard Gutowski
Professor Ian Kimber	Mr Bruce Petrie
Dr Richard McWilliams	Mr Rob Higgins
Dr Mike Simmons	Mr Alan Lynch
Professor Irving Taylor	Mr Simon Gregor
Dr Peter Thornton	Mr Paul Barrow
Dr Carl Waldmann	Mr Fred Huckle
Dr Paul Rylance	Miss Laura Murray
	Miss Rebecca Sugden (pm only)
	Mrs Daniella Smolenska (pm only)
	Miss Celina Cundy (pm only)
	Miss Michelle Kelly (pm only)
<u>Devolved Administration</u>	<u>Industry</u>
Mr Peter Phillips	Peter Ellingworth
Dr Sara Davies	Clive Powell
Ms Jemima Keyes	Mike Kreuzer

<u>Devolved Administration</u>	<u>Industry</u>
Mr Graeme Campbell	Doris-Ann Williams
	Nigel Brassington
	Maurice Freeman
<u>Observers</u>	Ray Hodgkinson
Ms Sylvia Shearer	Camilla Horwood
Dr Beverley Norris	Terry Prodger
Mrs Mary Hinds	
Professor Sue Hill	Charlie Perrins
Ben Doak	Rowan Bradley
	<u>Axiomed</u>
	Neal Defibaugh
	Jim Kuras
	Mr E Raymond S Ross

1. Welcome

The Chairman welcomed everyone to the meeting.

2. Apologies

Apologies were received from Professor Ian Learmonth, Dr Michael Gammage, Professor Simon Kay, Professor Matthew Cooke, Mr Christopher Morgan, Dr Martin Donnelly and Dr Stephen Hunter. Those apologies received from CSD members would be assessed and processed as some were deemed acceptable, and some unfortunate. The Chairman then introduced two guests: Professor Sir Alasdair Breckenridge, Chairman of MHRA and John Williams, past Chairman of CSD.

3. Conflict of Interest: Reminder

The Chairman reminded members of conflicts of interest and requested that if there was any part of the proceedings which an attendee felt the need to declare interest on, to leave the room for the duration of that session. It would not prevent them from engaging in the rest of the meeting.

4. Introduction and background to meeting.

The Chairman outlined the schedule of the meeting: The bulk of the business in the morning was to discuss developing the communication processes with users and patients. The afternoon's session would focus on regulation, particularly that surrounding enforcement and the CE marking process. The Chairman apologised for the late alteration to the agenda.

5. Main items

(a) Legal Constraints on MHRA (Melissa Coutinho)

Melissa Coutinho's presentation provided the committee with an overview of the legislation surrounding medical devices on the market, and in particular discussed information collection and halting availability. Melissa outlined the use of Compliance Notices, referring to Regulation 62(1) of the Medical Devices Regulations 2002, and discussed the considerations when using the regulation in a variety of situations. It was noted that Compliance Officers are designated by MHRA's CEO to determine whether a contravention of a safety provision has taken place.

Melissa Coutinho highlighted the enforcement powers of a Compliance Officer:

Under s.29(2) CPA Compliance Officers may

- a. Enter premises and inspect goods, (other than premises occupied only as a person's residence).
- b. Examine manufacturing procedures and testing arrangements.

Under s.29(4)+ CPA, Compliance Officers may, if they have reasonable grounds for suspecting contravention:

- c. Require the production of any records for examination and to take/copy any entry in records.
- d. Seize or detain suspect records and/or goods.

It is an offence under s.32 of the CPA 1987, without reasonable cause, to fail to give such an officer any information that he may reasonably require.

The presentation also covered the power to obtain information, and when to contemplate prohibition notices, and the use of test purchases to obtain information. Test purchases give enforcement authorities the power to ascertain whether or not the regulations have been breached. This is a useful investigative tool and a primary source of disclosure.

The options available if safety issues are raised with a device include Suspension orders which suspend the supply of any goods for up to six months, where it is suspected that a safety provision has been contravened and forfeiture orders which enforcement authorities may apply for where there is a contravention of a safety provision

Under the Medical Devices Regulations, (2002), restriction notices can be used where MHRA thinks it is necessary to restrict the availability of particular medical device(s), in order to protect the health or safety of

any individual(s). This restricts the availability not prohibition.

Under the General Product Safety Regulations 2005, recall notices can be used for consumer medical devices only. This is where there are reasonable grounds for believing that a product is dangerous and available.

Melissa Coutinho ended the presentation with a look at general inspection/investigation powers including powers of search whereby a duly authorised officer of an enforcement authority may at any reasonable hour and on production, if required, of his credentials, exercise any of the powers conferred by the following provisions of this section.

The Chairman thanked Melissa Coutinho for her presentation and welcomed questions from the committee to which Melissa Coutinho responded as below:

- As to how often legislative powers are used, the Agency works with a slide and scale approach, with voluntary basis and prosecution at either ends of the scale. In terms of numbers, Melissa Coutinho believed she received on average, one a week although there would be other cases that would not reach her.
- In response to a question regarding the UK establishing a similar system to that in the US whereby a statutory obligation is made in which manufacturers, who have received compliance, have a legal obligation to report adverse incidents to a central independent database, Melissa Coutinho felt that a similar system was imminent in the UK. The Regulation Accreditation Marketing Surveillance (RAMS) system is already on the table as a proposal and will see all incidents placed on a central register available to other member states. It is hopeful that this will be up and running before the end of next year.
- Tony Sant (MHRA) clarified there is already a regulatory obligation for manufacturers to report deaths or serious injury which are device related and the Agency has a good response rate from manufacturers
- Melissa Coutinho confirmed that manufacturers were prosecuted where they do not report serious adverse incidents.

The Chairman reminded committee members that MHRA itself welcomes reporting from CSD members about devices and groups of devices and encouraged members to report more.

(b) What has been achieved on the Medicines side? (Paul Barrow)

Paul Barrow presented on the surveillance systems used for medicines and in particular the yellow card scheme:

Yellow Card Scheme: Initiatives to promote Adverse Drug Reaction reporting

Yellow Card Strategy and data review

Further to a review of the Yellow Card scheme, the strategy was to focus on the key areas of education, motivation, facilitation and promotion. And look at defining outcomes and the setting of targets e.g. increases in reporting, use of electronic Yellow Card, Website hits.

In line with these four areas, activities to strengthen the Yellow Card Scheme are currently focusing on the following key areas

Electronic reporting

- Engagement with GP and pharmacy IT system providers
- Further improvements to e Yellow Card reporting system.

Educating reporters about the Scheme

- Outreach and Professional Education Unit, e-learning systems, schedule conference attendance and events such as MHRA-NICE study day, Yellow Card Centres.

Engaging with pharmacists to further strengthen the role of pharmacy in the Yellow Card Scheme

- through medicines use reviews
- Pharmacist promotion of patient reporting

Communicate and Publish

- Promote MHRA's work and trends in scientific publications and at meetings.
- Utilising the Yellow Card Centres resource

Patient awareness and involvement

- Engaging with patient groups and charities to promote the scheme
- Use of media - Life Channel advert, Electronic 'poster'
- Leaflet distribution to GP surgeries and pharmacies,
- External website info and links to eYC and MHRA
- Accessibility – languages and blind/partially sighted

The Chairman thanked Paul Barrow for his presentation and welcomed questions from the committee:

- Paul Barrow confirmed the Yellow Card Centres had been set up in the 1980's and over time their roles have changed. There are 5 regional centres which hold seminars/teaching sessions for healthcare professionals and are partly funded by MHRA.
- Referring to the possibility of using mobile phones to report incidents, there is a free phone number from which yellow card

information can be taken, but at the moment it is no more hi-tech than that. Establishing links/icons to mobile phones could be a possibility.

- Regarding general data being used by researchers and making it more accessible to researchers, Paul Barrow responded that he could not give exact figures but they do have requests from researchers to use data for detailed studies. Sir Alasdair Breckenridge commented on the establishment of the Independent Scientific Advisory Committee (ISAC) which has been in operation for the last two to three years. ISAC looks at a collection of data and how data can be put to best use by reputable investigators. Verification levels are used before the release of data and the main principle is that collected data is used to improve the health of the public in the best possible way.
- It was noted that an external review is underway this year comparing healthcare professional reporting with that of patients. Results from an internal smaller review suggests that patients tend to report on established drugs, whereas healthcare professionals tend to report on newer drugs.

(c) MHRA Communication Strategy (Simon Gregor)

Simon Gregor hoped to draw some general conclusions on MHRA's communication strategy and look at what is being done well and the areas for improvement.

Review of MHRA's communication strategy (2005 – 2007)

The MHRA's first communication strategy covered the key areas of communication infrastructure, benchmarks, media relations, its website, corporate identity, internal communications and cultural change.

The second communications strategy (2007 – 2010)

The second strategy looked at targeting and refining the infrastructure, working with pharmacists and other healthcare professionals, having more of a focus on consumers, widening its media reach and generating incoming information

The second strategy is also looking to focus on:-

- How do we establish the different needs of different stakeholder groups?
- How do we focus on what groups need?
- Widening media reach
- Generating incoming information
- Maintaining confidence in regulation

- People having access to regulations and an understanding of the workings
- Knowledge of who to turn to if concerned

From a recent survey it was concluded that the awareness of the regulation of medical devices by the public is lower than that of medicines and this is something the Agency is very keen to address. It was also clear that although people professed to know more about regulation than three years ago, their knowledge of the Agency was unchanged and very low, and their understanding of how to report problems did not include an awareness of the Agency's role. What does this mean for the future and what are the priorities?

Patient and Public Engagement

The MHRA has recently established its Patient and Public Engagement Strategy. As the Agency starts to engage more with patients and consumers one of the outcomes will be an increasing volume of unsolicited feedback and it is important to be mindful of responding to every enquiry.

MHRA website

The MHRA website is increasingly being used with its number of visitors and the volume of information published increasing, however this increase does bring about its own problems such as the difficulties in finding relevant information. The MHRA is looking to improve these situations by creating individual stakeholder pages and improving the search functionality and improve HTML links.

Marketing Team

It is crucial that not only is MHRA getting excellent information out into the public domain, but that it is actually influencing behavioural change amongst patients and clinicians. It is important to make information appealing, accessible and in real time and this is partly being done through Yellow card reporting, highlighting the issue of counterfeit medicines and devices, and the recent joint NICE-MHRA Conference.

Social Networking

Increasingly other organisations are using social network tools such as Twitter and Facebook to enhance engagement, dialogue and discussion. Organisations such as UK Parliament, the NHS and the Norwegian regulator are already using such forms of networking. Although not without risks, it presents a real opportunity for communication.

Turning to the future, Simon Gregor's aims for MHRA was to have excellent communications infrastructure, clearly crafted messages, and some excellent communications channels

The Chairman thanked Simon Gregor for his presentation and asked the Committee for any questions.

- It was commented that many people see NICE as the regulator and therefore there is a big job to do to explain what regulation is, and overcome the confusion with the public's perception of MHRA and other organisations
- Is there an opening for more general health service user groups such as the Scottish Public Patient Panel and Citizen Advice Bureau.
- A concern was raised about the instigation of negative campaigns against MHRA. It was noted that although this would be a challenge it was important to be realistic. Whether the Agency engages or not, there will always be the potential for negative campaigns which are already happening.
- It was noted that Devices Clinical have created a large network of contacts through the Professional Bodies and Royal Colleges.
- The Committee was happy that the training in the safety of devices has been included in the Foundation Doctor Programme at Postgraduate level. After discussions with Deans it was agreed that post graduate level was the most appropriate level for medical device training.
- It was commented that despite the good work of MHRA, there was still a long way to go with improving the awareness of MHRA among health care workers.

(d) Clicked Creative: Charlie Perrins & Rowan Bradley

How can the MHRA - CSD leverage social media technologies and trends to engage NHS Professionals?

Charlie Perrins and Rowan Bradley gave a presentation discussing social media technologies and how the MHRA may engage with such tools for communications. As well as outlining the variety of social media archetypes, they also illustrated the timelines involved, and the advantages and disadvantages involved.

Social Media Archetypes

- Blogging (writing blogs and seeding content to other blogs)
- Microblogging (posts have maximum length - e.g. Twitter)
- Media Publishing/Sharing (e.g. YouTube)
- Social Networking (e.g. Facebook, LinkedIn, MySpace)
- Wikis (e.g. Wikipedia)
- Discussion Forums
- Social Bookmarking (e.g. Digg, StumbleUpon)
- Smartphone/PDA Applications

The Chairman thanked Charlie Perrins and Rowan Bradley for their presentation and welcomed any questions from the committee to which Charlie Perrins and Rowan Bradley responded as follows:

- Regarding timelines and the distribution of information, it is possible to create different levels of access or create private pages but it is important to remember, once information is out in the public domain it is available to everyone.
- A committee member noted that as an end user and working in the NHS with computerised patient records, their Trust is also looking at hand held computers to be used on the ward at the patient bedside and it would be extremely useful to have links via Smart Phone/Iphone to access data and report incidents.
- It was noted that it is important to remember that as new information is being generated, older news is shifted down the scale which will lessen the likelihood of “clogging up” systems.
- The potential for libellous campaigns was raised, especially if sites such as Facebook and Twitter were incorporated into MHRA communication systems. It was noted that MHRA could have closed pages e.g. NHS pages, and once up and running users often become passionate about the content and are keen to maintain it to the highest possible standard. Again it was pointed out that smear campaigns are already happening. Simon Gregor will be attending a meeting next month attended by the Norwegian Regulator who will hopefully share their experience with social networking and he will be able to update CSD at the next meeting.

(e) Improving the MHRA’s Profile with Ophthalmologists in the Private Sector (Bernard Chang)

Bernard Chang’s presentation focused on MHRA’s profile with Ophthalmologists in the Private Sector, first looking at the different locations where Ophthalmologists practice and the systems in place regarding adverse incident reporting.

- NHS Trusts: Have MDLOS
- Private Hospitals: Should have MDLO or equivalent
- Smaller Laser Refractive Establishments: Unsure what practices are used for reporting

Bernard Chang discussed the existing tools in place to facilitate communication:

MHRA specialty specific Ophthalmology website which is linked to RCOphth website, however not all Ophthalmologists are members, especially those working in Laser Refractive Practices. How do we raise profile among this group of non-members?

Communication is the key:

- Obtain a contact list of all providers in the high street laser centres

- Attend their meetings, MHRA have stands
- Encourage reporting & appointment of a devices officer if not already done
- Regular reminders (6 monthly)
- Send targeted information and provide relevant information

Collaborating with other agencies

- NPSA has a reporting and learning service
- CQC and MHRA: annual inspections to look at “actioning” of alerts and reporting
- MHRA should give constant feedback to healthcare providers

**(f) How do GPs bridge the gap between the MHRA and patients
(Peter Thornton)**

Peter Thornton presented a paper to the CSD on how GPs bridge the gap between the MHRA and patients, showing how GPs should be in an ideal position to do this. He asked the question, do GPs have the appropriate information to communicate with patients? With respect to medicines it was felt they did and had support from Pharmacists and prescribing advisors, it is also easier to identify which patient to contact regarding a prescription of a medicine as opposed to which patient had been associated with a particular device and the particular type and model.

The benefits of electronic alerts and field safety notices were also highlighted, however Peter Thornton felt that GPs are bombarded with communications and information overload is a real problem. Better targeting that can be linked to records of relevant devices and the patients who are using them is necessary if important messages are to be understood and acted on appropriately.

Peter Thornton believed communication with GPs need to be relevant, targeted, eye catching and brief.

(g) Representing Allied Health Professionals on the Committee on Safety of Devices (Rosalind Ham)

Rosalind Ham presented to the Committee on Allied Health Professions, which was made up of 14 organisations and are regulated by the Health Professions Council. These organisations ranged from Art Therapists, Biomedical Scientists and Chiropodists/podiatrists to Occupational Therapists, Operating department practitioners and Radiographers. The following new professions are likely to come under regulation by the HPC in the future:

- Hearing aid dispenses
- Psychotherapists and Counsellors
- Dance movement psychotherapists

All of the 14 bodies have been contacted and so far 8 have responded and given a contact name for future correspondence. The following issues have been raised :

- Notification of the professional bodies
- Confusion with NHS Trust incident reporting to NPSA and MHRA for equipment issues
- Named MHRA link.
- Educating and notifying private practitioners/providers
- Review social service knowledge and reporting mechanisms
- Reporting to commercial companies about mechanical defects rather than correct reporting systems
- Notifying patients/customers/clients regarding equipment (especially with increasing self-care agenda and elderly population of equipment users)
- Poor record keeping of equipment issued both by NHS and dealers

The Chairman thanked Rosalind Ham for her presentation and remarked that he hoped the committee understood how MHRA needs CSD members to help in the work of communicating the importance of device safety and reporting adverse incidents to their individual groups.

(h) A glimpse at Flight Safety or Trouser Retention Systems (Geoffrey Crawford)

Geoffrey Crawford gave a presentation on Flight safety and asked the committee to think about safety and the regulation of the flight industry both within their own medical areas, and as it might apply to the work of the committee.

After a brief background of his personal career, he asked the panel why they would take an interest in flight safety as opposed to safety in other industry? (rail, road, shipping)

Looking at the number of incidents with BA aircraft from 1950's to the present day, this has greatly decreased, from 27 incidents in the 1950's to none in the 1990's. The chances of being involved in an aircraft accident with one of the 25 best airlines is 1 in 14 million

Why has this improvement in safety been achieved and what are the drivers in making the airline improve its safety record?

- Money (airlines can easily go out of business due to an accident)
- Potential for multiple fatalities
- Publicity
- Personal involvement (if there is an accident, who is going to be first on the scene?)

How has it been achieved?

Geoffrey Crawford illustrated the varying ways in which the airline industry had achieved this improvement in its safety record, ranging from a pervasive safety culture, huge investment, regulations (UK CAA, EU JARS, US FAA), training and simulators to the use of checklists, information gathering (recorders, FDR), information analysis and the publishing of reports and statistics openly and getting away from a blame culture. He finished his presentation using “trouser retention” as an illustration of the detail involved in the application of Flight Safety methods, and closed by reminding the committee of the Universal Law: “What can go wrong, will go wrong”.

6. Matters Arising/Action Points

- **Hazel Randall**

Hazel Randall gave a brief background regarding the Kappa/Sigma Medical Device Alert which she had presented on at the previous CSD meeting in July 2009. In 2005, the Company, Medtronic had issued an advisory “Field Safety Notice” (FSN) involving a group of Sigma pacemakers which had been found to be at increased risk of failure. The root cause of the failures was the separation of interconnect wires on the terminal blocks within the pacemaker circuitry. It appeared that the use of a particular solvent during the production of specific lots was responsible for this increase. At this time, the Agency issued a Medical Device Alert.

The patients involved were separated into 3 sub populations: Advisory, Non Advisory and Continued Vigilance Group. Medtronic then moved to Periodic Summary Reporting which was agreed with the Competent Authorities across Europe as routine practice and which only applied to the Advisory Group. Other groups were subject to individual incident reporting by the manufacturer to the Agency within the statutory time structure.

Hazel Randall updated the committee that the picture was fairly reassuring and since July MHRA had received:

- 9 further reports of Kappa incidents
- 7 further reports of Sigma incidents

Within UK, this is among 3500 potential affected pacemakers.

- 2 failures within the continued vigilance group, which is among 6500 potentially affected pacemakers in UK.

4 further reports on failures of Kappa and Sigma devices, although they are still waiting for the failure cause to be determined. In conclusion, Medtronic are due to issue an update to all customers with the latest information this month and MHRA will receive information on predictive failure rates at that time. MHRA has also taken steps over the last few months to ensure the manufacture is notifying MHRA of any incident before the failure cause had been determined (which means many may not be device related) and this has been seen as a real step forward.

- **Khalid Razak: Metal on Metal hip replacement issue**

At a recent CSD meeting the issue of soft tissue necrosis with metal on metal hip replacements was raised. The MHRA and BOA was tasked with investigating this issue to establish incident rates and provide advice. Further to the completion of questionnaires and surveys carried out by Orthopaedic Surgeons, the MHRA met with BOA and NRJR in September to discuss the data gathered and are now working on producing a report with recommendations. Khalid Razak hopes to report back to the CSD at the next meeting once the report has been finalised.

- **Dr Chris Brittain: Further communication with Healthcare Professionals**

Dr Christopher Brittain updated the committee on communication with healthcare professionals. The MHRA and NICE held its first joint conference in May, an outcome of which was the establishment of the Advisory Board for Trainee Doctors (TRAB) which has 12 trainee doctors and 7 representatives from MHRA. It will meet twice yearly in a similar format to the CSD and provide input from a trainee doctors perspective to promote adverse incident reporting, communication channels and tell the MHRA what GPs want from the MHRA as a regulator. The first TRAB meeting is on 20 November and one of the aims is for the committee to establish its own network system.

- **Dr Susanne Ludgate: Audit of Clinical Investigation**

Dr Ludgate updated the Committee on the auditing of clinical investigations. Further to accusations against the UK Competent Authority of being over stringent in its assessment and authorisation of clinical trials in the UK, MHRA has since put in place a system whereby the process is audited. So far, two out of the three audits have taken place this year and both agreed with the decisions reached. Dr Ludgate will be producing a more formal update to the CSD at the next meeting but wanted to say a thank you to those involved, who have put a great deal of work into the audits. Overall feedback has been good, and the audits have helped to make industry more confident in MHRA's decisions.

The Chair then summarised the morning's events: The presentations have raised a raft of issues which will take time to digest.

- Establish a formal CSD de-briefing meeting with MHRA following each CSD meeting, hopefully within 1 – 2 weeks in order to ensure that issues raised are actioned and progress.
- Set up several small working groups with CSD members and others to look at different areas:
 - (i) Communication
 - (ii) Structure of CSD
 - (iii) Safety (Possibly look at this at a later date)

The Chairman brought the committee's attention to the presentation stand which had an array of devices not fit for purpose and counterfeit devices which had been seized by the enforcement unit of MHRA.

The meeting adjourned for lunch at 12.45 and resumed at 13.45.

7. Minutes of last meeting

Mike Kreuzer on behalf of Richard Gutowski asked for an amendment to the line *"coming to possible future developments; these would include revision of the Device Directives, which had become out of date and inflexible"* (page 5). Richard Gutowski did not say they had become out of date and inflexible.

On page 11 of the minutes the General Nursing Council was noted. This should read the Nursing and Midwifery Council.

8. Attendance at meeting of the Committee on Human Medicines (Report from Chairman)

The Chairman reported back to the members on his attendance at the recent Committee on Human Medicines and he hoped to expand the linkage and communication between the two committees and had invited the Chair of the CHM, Sir Gordon Duff to attend a CSD meeting.

9. Main items: What Clinical Data is needed to support the CE Marking of a Medical Device? Recent trials involving the Freedom Lumbar Disc (Richard Gutowski, Bruce Petrie)

Richard Gutowski presented to the Committee on the regulatory and enforcement work carried out by MHRA and how the CE marking process works. In determining compliance with the Medical Devices Regulations issues may be raised over the clinical data used to support the affixing of a CE mark by the manufacturer for his device and this will be discussed further in the Closed Session.

Background:

- Medical Devices are regulated under 3 main EC Directives
- Directives outline certain compliance duties which the Member States are obliged to perform
 - Article 8 (93/42/EEC), safeguarding public health
 - Article 18 (93/42/EEC), non-compliant CE marking
- Manufacturers provided with copies of MHRA's enforcement policy when a compliance investigation is commenced on their product.

Richard Gutowski also noted the Devices Directives and the conformity assessment route which the Manufacture attending the closed session would have gone down to obtain CE marking for their product. They would have chosen an appropriately designated Notified Body either in the UK or in another Member State. That Notified Body would have been designated as being competent to deal with the product that the manufacture was producing. All Notified Bodies are monitored by their relevant Designating/Competent Authority. The Notified Body would then assess the manufacturer's facility, sampling the manufacturing processes involved which may include the design dossier if it was a higher risk product. They may not actually lift data on the particular product instead use sampling across the whole of the manufacturer's process). The Notified Body then determines that the data supplied by the Manufacturer is adequate for them to issue an EC certificate of conformity. Once a manufacturer has the EC Certificate they sign a declaration of conformity with the relevant Directive affix the CE mark onto the product which then has free access to 27 member states, 400 million users.

Compliance Unit

The MHRA has a dedicated Compliance Unit with trained compliance inspectors who investigate allegations of non-compliance. They investigate every complaint of non-compliance received on average 200 per year. There is also a risk based proactive programme whereby they investigate cases based on evidence obtained from vigilance reports, reports received from member states and members of the public. Richard Gutowski welcomed reports from CSD members on individual device types or family of devices where they felt on the basis of evidence a proactive investigation should be carried out.

Work undertaken by the Compliance Unit includes investigation of: unauthorised clinical trials, counterfeit medical devices (very difficult area to control as often a device is already in the supply chain, internet investigations, and all manner of alleged breaches of the medical device regulations

The Chairman thanked Richard Gutowski for his presentation and asked the committee if they had any questions to which Richard Gutowski responded as below:

- In explaining the relationship between the UK Competent Authority and a non UK Notified Body, Richard Gutowski confirmed that Competent

Authorities across Europe have come together to form a network whereby they liaise with one another if they have issues with a Notified Body from a member state i.e. they do not deal directly with a Notified Body from outside UK but through the responsible Designating/Competent Authority

- Following a concern raised that Notified Bodies only sample the work of a manufacturer rather than necessarily looking at the specific technical data for that device, Richard Gutowski clarified that it was dependent on the risk level of each device, the higher the risk then the more stringent the assessment
- Richard Gutowski gave a brief description of a Notified Body: a third Party Independent Testing organisation who is designated to assess information against the Medical Device Directives for the devices that they are competent in checking. The EU has intimated in a recent public consultation that there has been a “shopping around” culture where manufactures choose which Notified Body to use, but there does not appear to be any data to confirm such a claim. Currently some Notified Bodies are merging and there may be fewer, but larger Notified Bodies across Europe in the years to come.
- Richard Gutowski outlined the questions which manufacturers need to ask themselves when determining the classification of their device:
 - (i) Is my product a medical device?
 - (ii) Which class?
 - (iii) Which conformity assessment route to use?
 - (iv) Which Notified Body to use if one is required?

The EU Commission website lists all Notified Bodies and the areas they are designated for There are also authorised reps (who must be a registered company) who are designated by their manufacturer to act on their behalf which may include liaising with Notified Bodies.

- It was confirmed that it does seem to be a trend for a lot of trials to be taking place in Central/South America and the Far East rather than Europe. Provided that the data has been obtained within a trial that is acceptable and ethical, then it is not permissible to say it is any worse than a trial carried out elsewhere. Of more concern is the quantity of data that is used to support the CE mark. MHRA are expecting that the recent revision of the medical devices Directives will help in this respect
- It was also noted that MHRA does not see the clinical data that is generated from a clinical trial prior to it being submitted to a Notified Body as part of a conformity assessment process. The only way they see it is if there is an adverse event or concerns raised. It is not mandatory for manufacturers to present their final report to the Competent Authority.

The Chairman asked everyone who is not a full CSD member or MHRA staff to leave the meeting to guarantee confidentiality.

10. Closed Session

The Chairman thanked all for attending and again apologised for the disorganisation of the agenda and commented on the amount of work to be done, specifically in between CSD meetings.

11. AOB

There was no other business

12. Dates of next meeting: **25 March 2010**
 22 July 2010
 04 November 2010