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Committee on the Safety of Devices

3 November 2011

MHRA, 151 Buckingham Palace Road, London SW1W 9SZ

SUMMARY of MINUTES

Attendees:

CSD Members	MHRA
Dr John Perrins (Chair)	Dr Susanne Ludgate
Mr Bernard Chang	Dr Nicola Lennard
Dr Carl Waldmann	Mr Mike Peel
Mrs Christine Glover	Mr Philip Grohmann
Mr Chris Earl	Mr Andrew Crosbie
Dr David Sandeman	Ms Valerie Field
Professor Ellis Downes	Dr Catriona Blake
Mr Geoffrey Crawford	Ms Claire Dunne
Dr Graham Brown	Mr Roy Saunders
Mr Guy Alexander	Mr Tony Sant
Professor Ian Kimber	Mr Stephen Lee
Professor Irving Taylor	Dr Rosalind Polley
Dr Karen Facey	Mrs Daniella Smolenska
Professor Michael Gammage	Ms Sharon Knight
Dr Mike Simmons	Ms Rachel Bosworth
Dr Paul Rylance	Ms Anna Bussell
Dr Peter Thornton	Ms Susan Frade
Dr Richard McWilliams	Mr Graeme Tunbridge
Mrs Rosalind Ham	Mr Simon Holmes
Professor Stephen Halloran	Mr Doug McIvor
Dr Sheila Fisher	Dr Khalid Razak
Dr Steve Bennett-Britton	Mrs Sara Vincent
Dr Sheila Peskett	Mrs Marie Wade (Minute-taker)
	Mrs Carol Lowry (Minute-taker)
Devolved Administration	
Dr Martin Donnelly	Observers
Mr Pete Phillips	Mr Andrew Leverton
Mr Andrew Wong	Ms Emma Boakes
Industry	
Mr Malcolm Carlisle	
Mr Maurice Freeman	
Mr Michael Kreuzer	
Mr Nigel Brassington	
Ms Sarah Lepak (BHTA Dir. of Operations & Compliance)	
Mr Tony Reed (BDTA Executive Director)	

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1. Welcome

The Chairman welcomed everyone to the meeting and thanked them for attending.

3. Minutes of the Last Meeting

Some changes were proposed which have been incorporated.

4. Updates

i. Surgical Instruments - Professor Brian Toft

- A short update was given by Sarah Vincent on the actions that MHRA has taken regarding new surgical instruments. Following Professor Toft's attendance at this meeting where he highlighted his concerns, she mentioned that Professor Toft had since had a meeting with Simon Burns, and that MHRA had written back to Professor Toft with responses to the issues raised. She also mentioned that the CSD had canvassed Competent Authorities, and of the 27 countries which were approached 12 responses were received. Sarah ended her update by saying there were no major concerns raised by these countries regarding the quality of new instruments. Additionally, the issues were placed on the COEN workshop agenda at the last meeting but due to a lack of time it fell off the agenda. It will be re-examined at the next meeting.
- The Chair informed members that a proactive exercise has been done on this, from writing to Dental Officers, Chief Medical Officers and Chief Executives asking for information. The Royal College of Surgeons is currently carrying out a survey monkey which is going out to all surgeons asking if they have noticed any problems with surgical instruments..
- The Chair informed members that they will be kept updated as to whether there is any feedback.
- A member on the Council of the Royal College of Surgeons mentioned that this matter is a cause for great concern and said there are two important issues: Firstly, what responsibilities do the distributors have for checking the quality of the instruments? He said this is important because it is the distributors that various Trusts deal with, not the manufacturers necessarily. Secondly, is there any responsibility on behalf of the distributors of the instruments to check that their products are of the quality that is required?
- Another member made the point that control of distributors would be incorporated in the Recast although there were no controls on distributors at present.

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- The Chair indicated that it was up to the purchasing system within Trusts to use manufacturers who provide quality products, and the user has to be alert to when something goes wrong
- The Chair added that the problem with the surgical instrument manufacturers or the distributors is, if you find a problem with an instrument they are delighted to change it and give you a new one, and ultimately in the hospital you will then acquire a set of 100% perfect instruments, but unfortunately the quality control step is the hospital. The patient may have come to misadventure as a result of that first use or early use of a defective instrument and that is the difficulty, it is a small number that we are trying to weed out or investigate through this process.
- The Chair concluded that the MHRA had done everything necessary in terms of data gathering. He made the point that it was difficult to take action without evidence but this might be forthcoming from the RCS survey.

ii. IVD Working Party – Stephen Lee/Steve Halloran

- Members of the IVD Working party gave an update on some user guidance asked for by the CSD at the last meeting, for buying home tests over the internet and pharmacies etc. The CSD also asked them to provide guidance to Notified Bodies. (In the interim, a press release has been issued by MHRA about non-CE marked test kits for HIV, Hepatitis and sexually transmitted infections. The Health Protection Agency has written to known recipients to warn them that they had bought test kits that had not been CE marked. MHRA said they are also working actively to close down all the websites associated with this problem).
- The group is working with the MHRA Communications Division to develop a communications plan for sending warnings to users of home test kits.
- The group is also working with Notified Bodies putting together a draft guidance document to share with the BIVDA Regulatory Affairs Working Party on 9 December, and will be able to share it later with the wider CSD group.

ACTION: Share with Notified Body guidance document with CSD members when available.

iii. Medical Device Alerts – Christine Glover/Paras Shah

- Members were informed that a number of comments have been received both internally and externally about the Adverse Incident System and Medical Device Alerts. A meeting has been set up to look at all these comments and will be reporting back to the Committee once decisions have come out of that meeting.

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ACTION: Feedback at the next CSD meeting on the outcome of this meeting.

iv. Orthopaedic Mix and Match Outcome – Andrew Crosbie

- Andrew Crosbie reminded members of the CSD that at the July meeting that there had been a long and interesting discussion about whether the MHRA should be putting advice out about mixing and matching of hip replacement components. The outcome of that meeting was that the CSD did not feel advice from MHRA to the Health Service was necessary. It concluded that the best thing to do in the interim would be to write to the British Orthopaedic Association telling them what the current situation was, and ask them whether they would like to put out any advice of their own of the pitfalls of this particular practice. A letter was sent in early August. A reply is awaited. Andrew Crosbie informed members that since then, the MHRA have had a complex inquiry going with the National Joint Registry to try and tease out the data on this issue to see if they really can identify any problems associated with this practice in terms of increased revision rates. He summoned by saying, they have got back to us to confirm that based on the data available over the last 7 years of usage there is no significant difference between revision rates on mixed and matched combinations compared with ordinary one. The Chair mentioned that this has been further underpinned by some correspondence received which points out that the September 2011 National Joint Registry report demonstrates that the most commonly used hip replacement system, is a mix and match combination. He said, one manufacturer's stem and another manufacturer's cup, is performing just as well or better than the average.

Mr Crosbie went on to explain that feedback had been received from other centres that there may be some problem with Metal on Metal Hip

Replacements, not all with the cup and head where they rub together, but where the head joins onto the stem. He said the NJR have now asked to do an inquiry for us, to try and establish whether there is a special set of circumstances, where there are any problems. He concluded and said we are hoping to get this information in the relatively near future to see if there is any issues, and if there is, then we would consider whether we need to put out specific advice on this mix and match issue. In summary, there does not appear to be any general problems.

v. Vaginal Tape Workshop – Dr Ludgate

Dr Ludgate informed members that the MHRA had a very successful workshop on Vaginal Tapes for Incontinence. She said there were a significant number of adverse events, with concerns about how some devices have been brought to market with what appears to be minimal clinical data.

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The outcome from the workshop is on the website and is reported as an article in European Urology. MHRA are also in the process of producing a pamphlet for patients.

6. Main Items

i. A new Communication Strategy for MHRA – Rachael Bosworth

The Chairman introduced Rachel Bosworth, the new Communications Director of MHRA, to advise the CSD of the important changes and developments that are going to be happening with Communications at MHRA.

The Communications Director gave a presentation including an overview on work currently being carried out to review the MHRA communications strategy and how the MHRA could communicate more effectively.

Digital communications and how we use them was seen as absolutely critical to the way MHRA need to go forward with its communications.

She informed members that the Agency had started to use Twitter, and that the Executive Board have agreed to move forward with a digital engagement strategy. She concluded by saying there is a need to be looking at things like Apps etc. Going forward, it is intended that there will be a lead communication person for Devices who can know devices area much better and act as an interface between Devices as a division of the MHRA and Communications Division to ensure Devices get the right level of communications support. That person would work with the Devices Division to develop and implement a Devices to devise a Devices Communication Plan.

The second speaker, Anna Bussell from the Digital Communications team informed members that the website was launched in 2005, and since over 8,000 pages have been created, attracting over 200,000 unique visitors and almost 3 million page views per month. Areas for Patients and Public and the Pharmaceutical Industry have been targeted, and work is under way to develop the area for Healthcare Professionals. e-MDAs have been developed which are clearer and much easier to use. They are the primary tool for getting the MDAs out to the NHS through the CAS system.

She mentioned that the website needs an overhaul to allow Communications to bring in new elements, such as greater use of digital technologies. The new website homepage will be launched in January 2012 including greater flexibility to highlight key issues on the website.

Susan Frade (Head of Patient and Public Engagement), asked members for their feedback on the type of communications support needed by Devices. She said

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people do not know what they are supposed to do when they have a problem with devices, and they do not realise the MHRA is here to try and help them with these problems. The MHRA Devices should be the default point of contact for anything to do with Devices. She asked, who would the top audiences be? She stated that the healthcare professionals are the most ignorant of these potential audiences followed closely by other allied professions.

Christine Glover mentioned that she had had a meeting with the Communications Director, and said the group that they have set up is working exactly down this line to get the priorities right. She invited Communications to join the working group.

ACTION: Invite COMMS to sit on the working group.

A member asked if there is a standard PowerPoint presentation available. He said one of the items coming up at a post graduate meeting is that we could show a PowerPoint presentation to the Registrars or even to the under graduates. A corporate MHRA presentation, including Devices information, is currently being produced.

ACTION: Notify members when PowerPoint presentation and fact cards are available.

There was some discussion about the importance of the website and other digital communications in communicating effectively about Devices issues, including emerging technologies and trial safety.

The Chair mentioned that there is far too little understanding of just how effective the device regulatory structure is, and how effective the MHRA is. MHRA has an extremely effective mechanism for controlling devices and allowing new technology.

ii. A Proposal for an interactive Forum for the CSD – Geoffrey Crawford

Mr Crawford mentioned that in the last few years he has been involved in doing some Open University courses. He said this has brought him into contact with Internet Forums. He said he found these extremely useful as a way of communicating with other people about difficult topics, keeping track of discussions, and having a live discussion. One of the things that interested him about this proposal or idea is security. It is a little more secure than sending round e-mails. (Open up webpage). He said the thing about this Forum is that when I look at it, it highlights if they are posted or have been read yet

The Chair enquired whether people on the CSD would like to have such a Forum set up for them and who would manage it. He said there will be questions raised from time to time which we would want an input from the MHRA to answer.

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The Chair asked the CSD full members by a show of hands, who would like the possibility of a CSD Forum to be progressed. This could include minutes, papers, devices issues for the agenda and would be a way of trying to keep the Committee communicating between meetings.,

The COMMS director suggested that they treat this Forum as a pilot, as once it is there you can see how it is used. The chairman accepted this offer.

ACTION: Report back on progress of the CSD Forum.

iii. Recast

The Chairman introduced Graeme Tunbridge who is from the Policy division of MHRA who has been recruited to lead the Recast process in terms of its formulation and advice. The Chairman offered Graeme Tunbridge the personal and collective help and advice of CSD if he wished to use it.

Graeme gave an overview of where the Commission is in relation to proposals, and then go to discussion about papers that were circulated. He said MHRA are expecting to see proposals in the 2nd quarter of next year.

He informed members that prior to the proposals coming out, what the MHRA are doing at the moment is seeking to influence the Commission on some key priorities. He explained that in the EU arena he has to reflect the Government policies in every area, one important one is the Government's approach to Regulation, better Regulation and in particular, looking to reduce burdens on businesses and not bring additional costs on businesses. He mentioned that the table circulated is an attempt to summarise the key areas in different subject areas where the MHRA wants to see changes to the legislation.

The Chair reminded Graeme Tunbridge that in his initial document there was a suggestion that not much was needed to be done about Instructions for Use. The Chair said there is a very strong feeling from this Committee that there were considerable changes required in this area. He went on to say there has been a Medical Device Technology Forum which has now been distilled by Dr Lennard, and asked Graeme if he could personally debrief that with Nicola.

ACTION: Nicola to discuss with Graeme.

The issue of in-house manufacture was also raised and the importance of this in some clinical practices. The importance of maintaining the principles of in-house manufacture in the Directive were essential.

Issues relating to single-use devices and problems about re-processing were also discussed.

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A member mentioned that under the classification rules on page 1 there is mention of software as something to be considered for regulation. He asked the question, will such software ever be a medical device, or who will regulate it.

Graeme informed members that there is a European group that has been set up to look at this and there will be a guidance document being published soon, a MEDDEV on software. We will pick up the key elements of that and ensure they are reflected in the Regulations.

The Chair asked whether this process is going to cover preparation of devices for use, because we have come up against problems where the device for sterilisation is given in one country and then it is not the same as the advice that happens in the UK, and that has restricted the use of equipment. A member gave an example saying, when the device is manufactured in the United States, you get a sterilisation protocol that is not used in this country, and we then go back, that then becomes a compliance issue and they have to provide a sterilisation protocol that can be used.

The Chair stated that many of the important issues with regard to the Recast could be discussed via the CSD Forum.

The Chair asked Graeme if he would be prepared to join the CSD Forum in this respect. Graeme said he would be keen to do this.

ACTION: Invite Graeme Tunbridge to join the CSD Forum.

The Chair asked Graeme Tunbridge a further question, in his Recast/revision process there is an important part about trying to set up a more transparent post-market surveillance system. Graeme said, the UK is one of the parties that are really pushing for greater transparency.

iv. **Trending Outcomes – Roy Saunders**

Roy Saunders gave a short presentation and showed slides from a number of reports since the beginning of the financial year. For the most part they have increased. He explained that before last year they had never seen a month where they got above the 900 mark for the number of reports for a month. He said last year they had 3 months where they went over the 900 mark. This year we have already had 5 months over the 900 mark and a further month over 1,000 mark. Recent years shows a steady increase in the number of reports from manufacturers and a reducing number coming from professional users from the NHS.

Three trending examples were examined in detail (Simon Holmes, Sharon Knight), Catriona Blake)

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These presentations highlighted the success of the new trending procedures with identified trigger points in terms of convincing manufacturers that action needed to be taken important in terms of prevention and public safety.

7. Vignettes

i. Sizing of Catheters - Claire Dunne

Claire Dunne gave a short talk on the inconsistency of French sizing, which was highlighted to the MHRA through an incident report that we received. A surgeon was undertaking the treatment of a vascular blockage and was attempting to deploy a vascular plug through a 6Fr introducing sheath of a different manufacturer. On trying to pass the plug through the sheath he experienced a problem as it would not pass through. He managed to complete the procedure using a different sheath. On completing the operation he went back and checked the device labelling, the internal lumen of the sheath was slightly smaller than that required by the plug itself. The introducing sheath and the loader for the vascular plug were returned to their respective manufacturers for analysis. The analysis results came back and both devices were within specification. There is some difference in opinion on how French sizes are calculated. Many consider 3 Fr to be 1mm in diameter. However some people also consider the French size to be the circumference instead. The MHRA is not aware of any standards relating the French sizing. Although many may use $3\text{Fr} = 1\text{mm}$ in diameter as a guide, manufacturers manufacture outside of this tolerance and have their own manufacturing tolerances to consider as well. She summed up by saying, as a result of this incident the MHRA issued a One Liner to remind users that when they are selecting devices that they should check the metric and imperial dimensions as well as the French size. Going forward the MHRA plans to raise the issue of French sizing with the Standards Group on Labelling.

Richard McWilliams gave a short talk on French Sizing and stated that most people think the French size is three times the diameter of a device to take something in base 10 and turn it into base 3. That's option 1. The second Option is that the French size is the circumference of the structure which is being used, in which a 24Fr = 24mm circumference. $\text{Circumference} = \text{diameter} \times \pi$, a French size of 24Fr would be $24/\pi$ in diameter which would be less than 8mm. The French size should either be 3 times the mm or less than that. Most medical websites run with the $D(\text{mm}) = \text{Fr}/3$.

This matters when clinicians are putting things through introducers, a common part of Intravascular practice now, that things have to fit together.

He concluded that the French system of measurement is variously defined. The absence of certain definition probably explains the variability and dimensions of medical devices with the same French size and said we either need an agreed definition or, to eliminate this with some other system of measurement.

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ii. Laryngoscope Cross infection - Doug McIvor

Doug McIvor gave a short presentation on the laryngoscope cross infection. He informed members that the Greater Manchester Coroner advised the Minister for Health that there had been a problem, and a patient had died as a consequence of cross-infection due to the anaesthetic Laryngoscope Handle. The MHRA received a Rule 43 letter, which means the MHRA must take action or explain to him why we had not. The Coroner identified the cause of the infection that was passed on from a previous patient. The Laryngoscope Handles are either single use or reusable and the MAC Manual indicates an Intermediate Risk and requires sterilization or disinfection. There is good guidance from the Association of Anaesthetists. They prefer single use but they do accept reprocessing.

He concluded to say that after the Medical Device Alert was issued, we received a lot of comments. There were a lot of questions on the actual scientific basis of the investigation, however the instructions are quite clear. A lot of comments were that more specific guidance was needed.

Carl Waldmann spoke about laryngoscopes and laryngeal masks. We are not using the laryngoscope as frequently as we used to, as there are devices around called Incubating laryngoscope. He went on to say at the end of his talk, that the proposals are to have an effective national disinfection protocol. BAREMA may be instrumental in making sure if antiseptic wipes are going to be used, but there must be explicit instructions on how to disinfect the instrument.

iii. Self Sampling of HPV Virus Test Kits - Rosalind Polley

Rosalind Polley gave a presentation on self sampling on HPV (Human Papillomavirus), and whether or not it is being promoted as an alternative smear test. The test is basically a tampon, used to collect a number of cells close to the cervix. The tampon is then sent to a laboratory and they perform at test looking for viral DNA, in some cases that is looking for the integrated DNA. In the majority of cases they are looking for a number of high-risk subtypes, and there are some HPV subtypes that will not be tested with these tests.

The main concern MHRA had was that the advertising was misleading. Is it suggesting to the general population that they can stop going for smear tests and start using this test instead? There are a number of research papers looking at this, and research is ongoing as to whether or not it could in the future potentially replace smear testing or work alongside it. There is nothing known yet to say there is a good clinical utility for it as an alternative to the smear test. Our point of view would be if you are recommending an HPV test, it should be used in addition to the smear test.

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We have worked quite extensively with two manufacturers on advertising. They are quite happy to listen to us and change things when we go back to them. They have put on their website some specific indications that this is not the same as a smear test, to make it clear to users.

MHRA are in the process of developing some guidance on self testing which will cover self sampling and part of that will promote that you should always take part in national screening programmes.

We are working on an ongoing basis when we become aware of websites that might be misleading, working with them to amend the wording on the websites.

Mike Simmons gave a short talk, and mentioned that the key issue is between the diagnosis of cancerous or pre-cancerous cells, which we get from the smear test by comparison with the ability to demonstrate the viral genome of the virus that is thought to cause the majority, if not all of the malignancies. However the majority of young women will clear the infection without intervention and this will not lead to cancer. There is a big difference between identifying the presence of a virus versus cancerous cells. In fairness what we found when going through the four websites, all four are making that point that this would not diagnose cancer. The worrying side of the issue is that someone going down this route potentially will end up with a diagnosis that says they are HPV positive, but the smear test is negative and what does that mean for them. He said someone who has already decided they did not want to go for the screening programme, gets a test, goes and gets screened and ends up in this position from being worried, becomes even more worried and decides that she now needs to be screened on a regular basis. We have taken the whole issue out of the carefully controlled well managed process of the screening programme that recalls on a regular basis. When you reach the right age into uncharted territory where as a result of putting these tests on the market making them freely available we are wasting NHS resources trying to manage a whole set of worried women who have been drawn down this path.

He went on to mention an issue he thought was quite alarming. On one website they will sell you the whole pages costing several hundred pounds, you can have the first test, then a genomic test to see what's going on, as a result of that you have a smear test and they go on to address the issue of the in-between stages where somebody may be HPV positive but smear negative and offer a curative programme of nutritional advice etc.

In his summary he said, these tests need to be investigated within the realms of the screening programme so that we can begin to understand what percentage of the population is HPV positive.

Ellis Downes explained that the problem we have, is that we have been trying to identify a way of identifying pre-malignant disease of the cervix without women

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needing to come to see a healthcare practitioner, having a test which many women find uncomfortable and embarrassing. It is a good goal that needs to be looked at. However, he said the problem we have is that we cannot adequately collect pre-malignant cells, specimens in a tampon that has been tried and not reproducible. The HPV test is designed to try and identify high-risk subtypes which are associated with the development of CIN. The incidence of cervical cancer have fallen dramatically but it still remains that most women who get cervical cancer have never had a cervical smear. There is a huge message on public education, and the problem is that these websites are really selling the technology which does not have the underlying basic science to back up where they are going. In his summing up he said there are a number of big population trials which are nearly completed and within the next 5 years we will be following women up after cervical screening, in a very different way, maybe HPV, or perhaps self-collection we just do not have the data at the moment to properly do it.

8. Further Updates

i. Education Committee – Christine Glover

Christine Glover gave an update on the Education Committee, and informed members of the progress made with this project. She said there has been a meeting with the sub-group at the beginning of September. She had also met with the Communications Director and briefed her about what the group thought what was needed on education. Two short presentations have been produced on the essential facts about devices. She said the point of this is a basic form, which is then honed according to the audience we are going to see.

Such basic facts on cost of Medical Devices to the Health Service and cost of litigation were important in speaking to Trust managers and financial managers since they are interested in litigation, risk and clinical governance.

ii. Audit of Clinical Investigations – Daniella Smolenska

Daniella gave an update on the annual CSD Audit of clinical investigations. In July she presented results of the 2010 CSD Audit which reviewed clinical investigations received by MHRA in 2009. At this meeting Daniella summarised the findings of the 2011 CSD Audit, which reviewed clinical investigations received by MHRA in 2010. A further 3 applications had been selected.

There have been a number of recommendations and comments made. Those have been around the use of external assessors and there has been a suggestion that we need to identify further expertise in a number of areas. Also acknowledging the problems that we have faced finding the experts that we need on a 60-day process and that when we do they are often not available for the full 60 days. Comments were made also to the adherence to our procedures. There

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were a few minor deviations on a couple of these cases and the CSD have given us suggestions on how we can improve our procedures and how we can improve the guidance that we give out on our website for applicants.

The MHRA will go through the recommendations and aim to come back at the next CSD meeting to provide the CSD with a run-through of what those recommendations were and what our corrective actions have been.

ACTION: Feedback on recommendations and outcomes from this at the next CSD meeting.

The Chair thanked all the CSD members involved in these audits.

iii. Medical Device Driving Licence – Mike Peel

Mike Peel informed members that MHRA have moved forward with the MDDL quite significantly and have nearly 500 users registered on the MDDL website. The NHSLA are now pushing Trusts their staff to get on board with this. They want to be able to export the licence and their certificate from the MDDL once they have been produced into the electronic staff records. We will be visiting the electronic records people to see how this can be achieved.

He finished by saying we are hoping to move from the pilot stage into a launch, and are looking at 2 April next year.

iv. Metal on Metal – Khalid Razak

Khalid Razak gave a short update on this and explained that the Expert Advisory Group looking at the issue of soft tissue reaction associated with the Metal on Metal hip replacement produced a report with their recommendations in October 2010. The group decided to meet again in June this year to consider any new evidence and intend to produce an update the report. We have collected comments from the group and incorporated them into a draft report which will be circulated to the Expert Advisory Group for further comment.

v. Medical Device Technology Forum – Nicola Lennard

Dr Lennard gave an update and informed members that the Medical Device Technology Forum Instructions for Use was born out of the CSD, which tabled the guidance document produced from here at the CSD. She said she would be grateful for any feedback on that document, or ideas on how we take this forward, . Plans at the moment consist of inputting into the Recast and promoting the document with trade associations, and secondly we are planning to take this towards Standards meetings as well.

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Dr Ludgate also informed members that MHRA have a very interesting Medical Device Technology Forum meeting tomorrow in this area and the subject is bringing Orthopaedic Hip Implants to Market. This has arisen because of concerns about the number of hip implants that have come to market and then failed. . There are a number of problems that do not show up instantly, so short-term clinical trials really do not bring out the major problems and you need very good long-term post-market surveillance.

The Chair thanked members for their attendance and input to the meeting.

9. **Dates of future meetings**

1 March 2012

19 July 2012

22 November 2012