COMMITTEE ON THE SAFETY OF DEVICES
20 March 2014
MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ

CSD	
Dr Sheila Fisher	Mrs Rosalind Ham
Mr Guy Alexander	Professor Ian Kimber
Dr Steve Bennett-Britton	Professor Richard McWilliams
Dr Graham Brown	Dr Paul Rylance
Mr Geoffrey Crawford	Mr David Sandeman
Professor Ellis Downes	Professor Irving Taylor
Dr Karen Facey	Dr Peter Thornton
Professor Michael Gammage	Dr Carl Waldmann
Professor Stephen Halloran	
MHRA	
Sir Gordon Duff	Roy Saunders
Mr John Williams (NED)	Valerie Field
John Wilkinson	Rob Higgins
Neil McGuire	Camilla Fleetcroft
Philip Grohmann	Mark Grumbridge
Tony Sant	Louise Loughlin
Andrew Crosbie	Carol Lowry
DEVOLVED ADMINISTRATIONS	
Dr Martin Donnelly	Mr Eddie McLaughlan
Dr Gavin Hughes	
INDUSTRY	
Mike Kreuzer	Nigel Brassington
Terry Prodger	

SUMMARY OF MINUTES

1. **Welcome**

The Chair, Dr Sheila Fisher, welcomed everyone to the meeting, and extended a warm welcome to Sir Gordon Duff, Chairman of MHRA, Dr Neil McGuire, new Clinical Director, Devices, and Dr Camilla Fleetcroft to the meeting.

Apologies

Apologies were received from:

Dr Ian Hudson, Mrs Christine Glover, Dr Sheila Peskett, Dr Mike Simmons, Mr Bernard Chang, Mr Ray Hodgkinson.

2. **Conflicts of Interest**

No conflicts of interest were declared.

Notification of Any Other Business

i. Members will shortly receive the European Commission's Scientific Committee on Emerging Newly Identified Health Risks (SCENIHR) review on Metal-on-Metal Hips. If any members have any comments after reading the document, please contact Sheila Fisher, John Wilkinson or Neil McGuire.

ii. The core of the agenda will focus on receiving the Stephenson Review on access to clinical advice and commenting on the implications. To inform this discussion Dr Graham Brown will outline an initiative which is taking place within the dentistry community.

3. **Minutes of the Last Meeting**

The minutes were accepted as a true record of the last meeting.

4. **External Review of Clinical Input to Medical Devices**

The Chair outlined the process that had led up to the decision to commission the external review and expressed thanks to those who had been so energetic in getting the process off the ground. The process had been entirely helpful and constructive and the result is something that the CSD can be proud to have contributed to.

The Chair invited Sir Gordon Duff to comment. He described the Stephenson Review as epoch-making in many ways within devices regulations in the United Kingdom, and certainly to the MHRA. The Panel and Professor Stephenson were extremely well supported by the Secretariat in the Agency and Sir Gordon expressed his thanks to those who supported this review which was completed over a very short time frame. Sir Gordon specifically recognised the role played by the Chairman and members of the CSD who contributed in a major way to getting the best possible results from this review All of the recommendations and comments have been accepted by MHRA and the plan of implementation will be effective and timely. The deliberations of the CSD will be valuable in shaping the Agency's response.

John Wilkinson endorsed Sir Gordon's comments regarding the review. He thanked the CSD collectively for their role in initiating the exercise and felt that the review would help the MHRA raise the profile of devices issues in the community generally and within the MHRA itself. He reflected on the need to build on the network of advisors that have been so important to us over the years and create more robust governance around the appointment and development of the network.

He went on to briefly outline the main areas included in the report and its recommendations. It is acknowledged that some of these can be addressed within the Agency and others require wider partnership. Each of the recommendations and their implications for the Agency were discussed.
The report made recommendations in the following areas:

Key Recommendations

Organisation of clinical advice input, resources and leadership

1 The MHRA must take devices as seriously as medicines: Create a formal mechanism for clinical advice input to MHRA.

2 Review the MHRA resources needed.

3 Ensure that adequate clinically trained staff are included in the MHRA staff.

4 Develop and manage the network of clinical advisors.

5 Develop the existing collaboration with EU bodies with similar aims to the UK MHRA.

Other Recommendations

Collecting and using device incident data

6 Build links with the Clinical Commissioning Groups to help improve the flow of information on safety and performance of devices.

7 Improve and simplify the way incidents are reported, aiming to obtain reports on all device incidents.

8 Develop means by which devices implanted in patients can be identified by their Unique Device Identifiers, and means by which patients with specific devices can be traced.

Communications and partnerships

9 Improve communication about adverse incidents to patients and the public, clinical staff, clinical scientists, hospital managers and professional bodies.

10 Develop improved communications about the MHRA's role in ensuring the safety of devices with clinicians, clinical scientists, hospital managers and the public.

11 Develop collaboration with relevant English bodies, including NICE, NHS organisations, Public Health England, with the UK Academy of Medical Royal Colleges and also with devolved administrations.

Future developments and emerging challenges

12 Support the safe introduction of new and innovative technologies into clinical practice.

.This review builds upon recommendations set out in the review by Earl Howe into the agency and Department of Health's actions in relation the PIP breast implant scandal (*Poly Implant Prothèse (PIP) silicone breast implants. Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health*) and makes proposals about the agency's role in enhancing reporting of adverse incidents in the NHS and private sector. Mr Wilkinson then commented on recommendations that described the agency's role in informing clinical practice and training of clinicians and that these required investment in pro-active relationships with professional bodies.

The final recommendation focused on the MHRA's role in supporting the development and safe introduction of emerging technologies.

The Stephenson Review will be published as soon as a suitable window is identified and the agency is committed to providing a full response to the recommendations before the summer break.

A number of helpful comments were made by members of the committee and these will be taken into consideration as the agency develops plans and prepares a formal response to the review. Comments included:

- In order to improve reporting it will be important to define roles and responsibilities as well as ensuring that information flowing from the MHRA is not lost in the general correspondence. For Trusts, Medical Directors and Chief Nursing Officers have pivotal roles in ensuring that information is acted upon.
- Another comment reinforced the need for two-way communications between Trusts and the MHRA and ensuring that all staff knew who to report to and why.
- Current work with the dental community was cited as a good model for building pro-active relationships which encourage dialogue on emerging matters of concern.
- One member reflected on a point made in the report that patient safety is a multi-stakeholder activity and, along with the clinical professionals, public, patients and carers need to be encouraged to play their part.
- The committee was reminded of the importance of professions allied to medicine and nurses to delivering improved safety and regretted that more emphasis had not been placed on this in the report. Sir Gordon Duff reflected on the importance of this and suggested that this be comprehensively addressed in the Agency's response to the report. Members are aware of the national agenda and the increasing use of ever more complex devices in a community setting. Ensuring robust links to both healthcare professionals and patients and carers in that setting will be part of planning for the future.
- Increasingly active implantable technologies have the capability of monitoring the patients' wellbeing on a continuous basis and signalling potential failures in advance of them happening and this facility could work to shorten reporting processes and signal needs for remedial action ahead of time.
- The approach to this is to get Professional Bodies and ourselves working together to identify the opportunity and bring emerging issues forward proactively..
- Committee members expressed willingness to offer expertise in specific areas and to work more formally with the MHRA to help them with matters arising from the report.

The Chair welcomed the report, acknowledging that the review had taken during a period when the Agency is going through a period of leadership and operational change. This was complemented by unprecedented change in the NHS in England and within the devolved administrations, all of which demands that the MHRA works evolves to meet both the new architecture and challenges. She reflected on a strong feeling of just how much there is to do and how much we are going to have to work together to achieve outcomes which enhance the ability of the Agency to improve patient safety. The Committee then formally welcomed and endorsed the report.

Sir Gordon Duff reflected that the review arose from the CSD and its legitimate concerns for the future welfare of the Agency and its capacity to execute its responsibilities. He thanked the Committee for their efforts and suggested that their legacy would be influential in shaping the Agency in the future and, for which, he could express sincere thanks on behalf of the Agency and its Board.

5. **Patient and Public Involvement in MHRA**

Dr Janine Jolly described the scope and importance of effective patient and public involvement. She described three distinct but inter-related groups.

- Patients who have acute contact with health and healthcare services.
- Patients with lift-limiting long-term illnesses, co-morbidities, serious health conditions that require them to interact with health and healthcare services frequently and over long periods of time.
- Wider public, public opinion, public perceptions. This is important in terms of public policy. Public opinion informs public policy.

Effective engagement can be characterised as a power shift away from expert knowledge alone towards a partnership which respects the patients and public perspective, utilising their experience of what it means to have that condition. Partnership and participation leads to patients making decisions with professionals. This is important for MHRA because there is a changing social policy context where patients have higher expectations than before regarding the efficacy of healthcare science, relationships with professionals and what they can expect from the overall patient experience. Engagement and patient involvement facilitates a better dialogue towards better products, better use of products and improved levels of reporting.

To this end the Agency is developing a pilot Patient Consultative Forum. This is to bring together recognised patient groups into a forum where we can develop a meaningful two-way dialogue with those groups. A number of items have been taken forward as a result of the patients bringing issues to the Agency's attention.

Feedback from the Committee included:

- The increased prevalence of cosmetic interventions indicated a very strong need for the Agency to develop a dialogue with those exposed to new and emerging risks.
- There has been a sense that the devices part of the Agency only engages with patients and the public when something goes wrong. This initiative is to be welcomed as a source of more a pro-active and exclusive strategy.
- One of the devolved administrations suggested that the paper presented was disproportionately orientated towards England and that the devolved administrations had their own processes which would need to be accommodated.
- Expanding the role of patients in reporting adverse incidents was one means to address the challenge of under-reporting.
- Can the MHRA use lay members of professional bodies as a source of advice and access to patients in the community?
- Some concerns were raised in terms of the cost of implementing such a plan and whether the resources would be available.
- Whatever is put in place needs to be inclusive reflecting the fact that some groups have little or no real voice.
- In discussion with Academy of Medical Royal Colleges it was suggested that one of the more developed models was the NHS England Patient and Public Group and that this might be a good source of lay input to a future advisory body.

- Historically the MHRA has focused distribution of Medical Device Alerts towards professionals in order to ensure that messages are tailored to match the needs of patients but there are increasing indications that there should be more frequent direct communications between the Agency and patients and carers. One suggestion was that the MHRA should increase the use of patient charities as conduits.
- It was felt that the new advisory body to the MHRA could provide strategic advice on how to develop channels of communication and where and when the clinical route should be complemented by a direct to patient exercise.

CSD members expressed support for work in this essential area and a willingness to contribute as the agenda progresses.

6. **Clinical Audit**

The number of clinical investigations submitted to the Agency for approval has not increased significantly over the past few years but the number of amendments that we have to consider has grown very substantially and these often require considerable input both internally and from expert advisors. There has also been a steady change in mix of applicants with industry submissions declining and academic institutions rising.

One member of the Committee raised the issue of professional liability for advisors and indemnification by the MHRA. As previously advised:

> "Committee members, that have been properly appointed to represent an appropriate specialism, who act honestly, reasonably, in good faith and without negligence are indemnified as regards personal civil liability which is incurred in the execution of their committee functions".

This year's audit of the clinical investigation process was increased to five cases versus three in previous years. It was felt that this allowed a better range of types of regulatory challenge to be

considered. The chair wanted to recognise the fact that the audit team were highly appreciative of the amount of work done by both the ERA team and clinical team in helping to ensure that investigations were well designed. The review concluded that all of the decisions made were appropriate and the members of the Committee confirmed that the audit was complete with all outstanding queries resolved to their satisfaction.

Two issues of interest arose out of the audit. The first was in relation to access to statistical advice and the audit team confirmed that they thought that use of statisticians was appropriate and that the resources provided by the medicines team at the Agency were generally helpful but that the division should be careful to ensure that this situation was kept under review. It was confirmed that it was appropriate for the Agency to advise on the power of studies and decline to permit studies that would be unlikely to provide statistically valid evidence. The second issue related to training of assessors and it was suggested that the Agency explore the possibility of developing on-line training for assessors.

The Agency team reaffirmed the value of the audit process as a key component of the MHRA's quality systems and as a source of ideas and more general advice.

7. **Earl Howe Review**

John Wilkinson updated the Committee on progress with response to the Howe Review of the actions of the MHRA and DH with respect to the PIP breast implant scandal. A formal response was published on the anniversary of the review's publication:

http://www.mhra.gov.uk/home/groups/comms-po/documents/news/con286825.pdf

Mr Wilkinson went on to report that, while many of the actions were completed, work was continuing on some of the more strategic initiatives particularly around adverse incident reporting, communications and stakeholder engagement and developing the EU system and its management. Many of the themes are entirely consistent with similar issues raised as part of the Stephenson Review into the Agency's access to clinical advice. These activities are also embedded in the MHRA's Annual Plan.

The Committee discussed the extent to which current legislation restricted the exchange of information amongst stakeholders and wished to explore the possibility of future advisory groups having access to both the output of EU Vigilance Conference Calls and provision of information about adverse incident s to professional bodies on a systematic basis so as to enhance the dialogue on areas of potential concern.

The Agency is hoping to develop a dialogue with industry about releasing non commercially sensitive information ahead of the anticipated changes to the regulations which will enhance transparency.

The Chair commented on the good progress being made and the leadership role that the Agency has and continues to have on both the European and global stages..

Andy Crosby updated the Committee on the recent publication of a report on metal-on-metal hips by the Scientific Committee on Emerging and Newly Identified Health Risks (**SCENIHR**). The analysis and advice was entirely consistent with the work that the MHRA and British Orthopaedic Association had carried out and published last year.

8. **Future structure and functions of Devices Expert Advisory Group and transition planning.**

As a preface to discussions about the future role and composition of the Devices Expert Advisory
Two current initiatives were described:

- Working with stakeholders in the area of dentistry to create a collaborative group focused on device related issues. This includes the Chief Dental Officer of England, the General Dental Council and representatives from the primary practitioner groups.

- Meeting with Royal College of General .Practitioners to explore opportunities for stronger links in light of increased care in the community and the fact that it is GP's who often see problems with implanted devices before the specialists do.

These emphasised the importance that the CSD has had in brokering relationships for the Agency and it was envisaged that the new advisory body would fulfil a similar function as well as providing strategic advice.

It was agreed that any new advisory group would need a high calibre and influential independently appointed chair. The CSD concurred that the key areas that any new committee needed to focus on were improving reporting and helping the agency with analysis and subsequent dissemination of lessons learned so as to reduce the potential for patient harm. Tony Sant described the work that the MHRA are doing with NHS England and NRLS (National Reporting and Learning System) to make reporting both simple and fully integrated. The work needs to address both the practicalities of reporting and barriers that stop people reporting and this would benefit form a strong institutional push from professional bodies. There were also comments about the MHRA's capacity to manage a large increase in reports.

Understanding the existing and emerging network of safety committees in the professional bodies would be important in designing an effective architecture to work with the clinical community without duplicating work. There will need to be a clear focus on both safe innovation and understanding the practicalities of the use of devices in routine practice.

Members were keen to support the division in linking to clinical and patient groups to address the wider aspects of the report. The strong external links and partnerships that they bring is key to encouraging dialogues and partnerships in areas where the MHRA has expertise but which are beyond its direct influence and core responsibilities. The common aim is to improve patient safety. Such areas include training and education and innovation and research in devices and technology.

The Chair described very mixed feelings in bringing the term of the Committee to a close. She was sad to see the passing of a very energised and active group who had contributed so much to helping the Agency function and develop. On the other hand, the Committee had sown the seeds for a better and more effective future reflecting the enormous changes that had taken place in both the environment and the MHRA since the committee was originally founded.

The Chair then thanked the Committee for their hard work and valuable advice. She also asked for volunteers to stay involved in an interim capacity during the implementation of the Stephenson Review recommendations.

Meeting closed at 15:35.