SUMMARY OF THE DEVICES EXPERT ADVISORY COMMITTEE MEETING HELD ON THURSDAY 2 JULY 2015

Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the DEAC remains confidential at the date of this summary and will remain so until a final decision has been taken. There is no overriding public interest to release such information in advance of the regulatory process being completed. Any request for future information should be made direct to the MHRA (via info@mhra.gsi.gov.uk) and will be considered in accordance with the FOI Act.

The Devices Expert Advisory Committee (DEAC) discussed the following agenda items:

Introduction by the Chairman of the Group

The Chairman reminded Members and observers that the papers and proceedings are confidential and should not be disclosed and there was a short discussion on the confidential nature of the work.

Function and structure of MHRA Devices Division

The Committee heard a presentation on the Role of the Devices Division.

The MHRA Interim Committee on Safety of Devices (CSD) Chair provided an update and overview of the last CSD meeting.

The Director and the Clinical Director of Devices provided an update of the Agency's progress in response to the Independent Review on MHRA access to clinical advice and engagement with the clinical community in relation to medical devices.

The Chairman set the scene regarding the functioning of the Committee.

Current issues, priorities and programmes

The Committee heard presentations on:

- post-marketing surveillance and the MHRA partnership in improving patient safety
- the overview of the regulation of next generation sequencing technologies that are used in clinical genomics
- the need for a Leadless Pacemaker Expert Advisory Group

The Committee also received updates on:

- Unique Device Identification and the implementation of GS1 standards
- metal on metal hip replacements

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Procedural Items

In addition, the Committee completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies and announcements.

i. A list of Members and invited experts who attended the meeting is at **Annex A**.

ii. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

iii. On Thursday 2 July, the meeting started at 10:30 and finished at 14:50.

The next meeting will take place on 5 November 2015 at 10:30.

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ANNEX A

MEMBERS ATTENDED:

Chairman

Dr Peter Nightingale

Members

Professor Derek Alderson

Mr Gerard Dean

Dr Kathleen Ferguson

Dr Peter Groves

Professor Ian Kimber

Ms Mirella Marlow

Mr Edward Morris

Ms Sara Payne

Dr Iain Robertson

Dr Carl Waldmann

External Advisor

Dr Sheila Fisher