TGA Regulatory Compliance Committee

Meeting 16 – Wednesday 16 April 2014, 10.00am

Executive Board Room

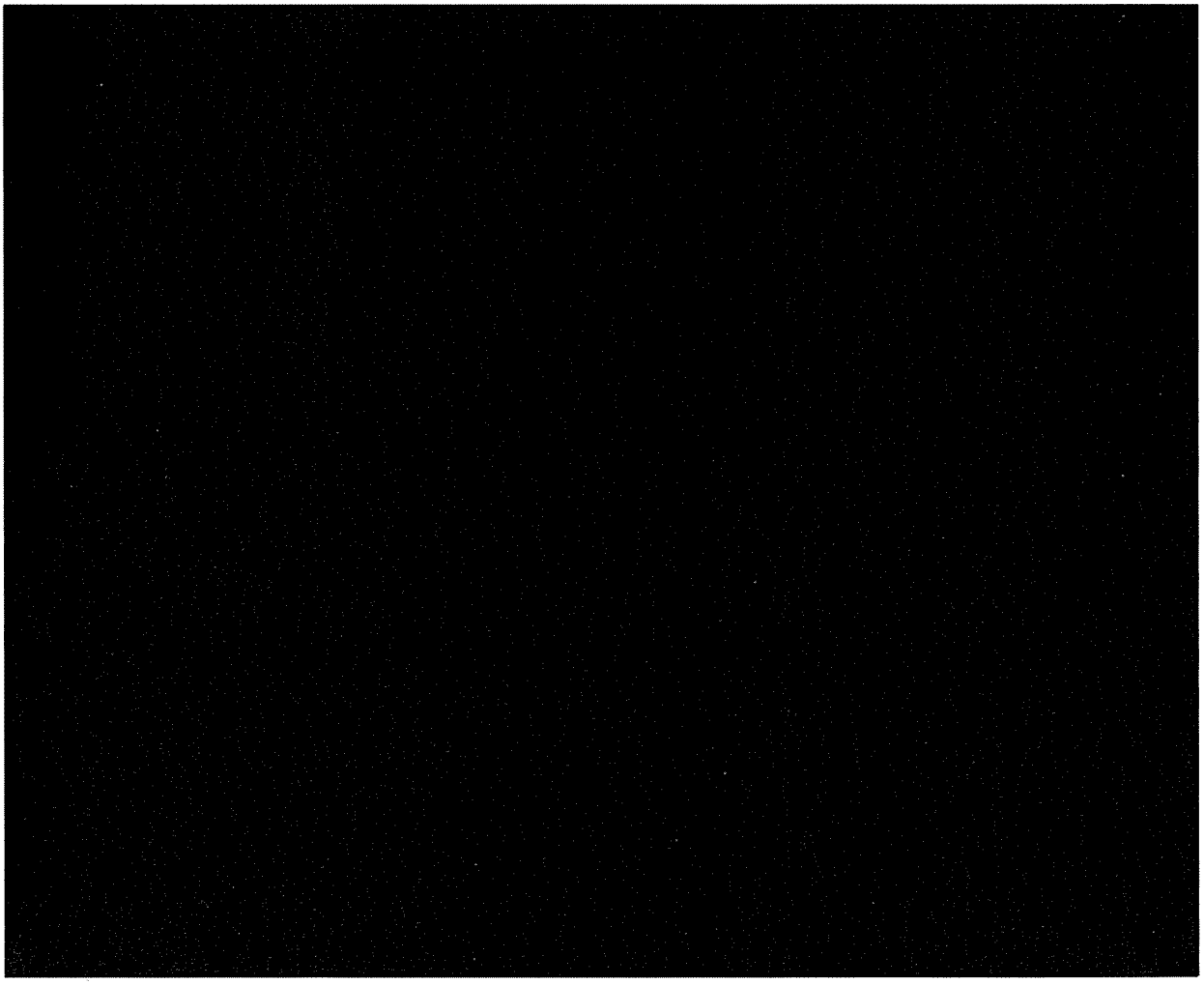
Final Meeting Outcomes

Participants:

Chair – Larry Kelly, Head, Monitoring & Compliance Group
Tony Hobbs – Principal Medical Adviser
Lisa Studdert – Head, Market Authorisation Group
Mark McDonald – Office of Laboratories and Scientific Services (OLSS)
Trisha Garrett – Office of Complementary Medicines (OCM)
Irina Tsyganova (for Andrea Kunca) – Office of Devices Authorisation (ODA)
Katherine Gray (for Jane Cook) – Office of Product Review (OPR)
Eric McIntosh – Regulatory Compliance Unit (RCU)
Harry Rothenfluh – Office of Manufacturing Quality (OMQ)
Vimala Srinivasan – Legal Assistant
Secretariat: MCG GSU – Linda Martin, Emily May

Apologies:

Philippa Horner – Principal Legal Adviser
Jane Cook – Office of Product Review (OPR)
Andrea Kunca – Office of Devices Authorisation (ODA)



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The report from OMQ was noted. Dr Rothenfluh provided an update to the Committee about some recent issues with foreign manufacturers.

OMQ will review their risk management framework in light of these recent issues. In future, OMQ will endeavour to conduct more intelligence-driven inspections. Dr Rothenfluh noted that this is the approach taken by the FDA and MHRA.

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