Draft Minutes for Blood Consultative Committee (BCC) Meeting
2nd October 2014, 13:00-16:00
MHRA Buckingham Palace Road Offices, RT 410

Attendees:

Shubha Allard (NHSBT)
Sheila MacLennan (JPAC)
Chris Philips (NHSBT)
Chris Elliot (IBMS)
Marie McQuade (BBTS)
Graham Rowe (Wales NHS)
Steve Moore (NHSBT)
Ann Hosken (Wales NHS)
Allan Morrison (NTLMS)
Caroline Lewis (Wales)
John Barker (GNHT)
Samuel Machin (UCL)
Tony Docherty (SNBTS)
Paula Bolton-Maggs (SHOT)
Joan Jones (Wales NHS)
Stuart MacDonald (MOD)
Alison Watt (SHOT)
Cyril Taylor (TDL Pathology)
Angela Macaulay (NIBTS)
Bill Scott (Scotland)
William Hughes (SNBTS)
Elizabeth Reaney (Wales NHS)

MHRA:
Michelle Rowson (IE&S) – Chair
David Carter (IE&S)
Vivian Rowland (IE&S)
Chris Robbie (SABRE)
Kevin Page (IE&S)
Ian Rees (IE&S)
Stephen Grayson (IE&S)
Graham Carroll (IE&S)
Mike Dawes (SABRE)
Beverley Malin-Smith (IE&S) - minutes

1. **Apologies Received:**

Sandra Gray (Nurse Representative)
Liz Carroll (Haemophilia Society)
Adrian Newland (NHSBT)
Johnathan Wallis (BSH & NHSBT)
Jot Hyare (NTLMS)
Ann Benton (NHS Wales)

MHRA:
Gerald Heddell (IE&S)
David Churchward (IE&S)
Richard Funnell (IE&S)
Mark Birse (IE&S)
Andrew Hopkins (IE&S)
Graeme McKilligan (IE&S)

2. **Introductions and Apologies for Absence**

Michelle Rowson opened the meeting by thanking everyone for attending and welcomed any new members into the meeting. It was agreed that the apologies for absence would be recorded in the minutes. Michelle Rowson reported that the order of agenda would be changed to enable Ian Rees to present the Regulatory update item first due to Ian needing to leave early to attend a meeting with international regulators.

3. **Approval of Minutes from previous meeting held 5th March 2014**

Typographical errors were noted for amendment under items 3 and 4.

Matters arising from October 2013 Minutes

Item 4 – Request for SABRE to provide examples of best practice and share experience to enable

lessons learned to be implemented. SABRE will continue to work on how data can be presented. It was noted that the quality of reports received will have an impact on the available information that can be presented.

Item 6 – Request for Blood representative to join Inspectorate compliance improvement project to ensure deficiency data and lessons learned examples meet the needs of Blood stakeholders. Michelle Rowson reported that to date, David Churchward had not received any nominations from Blood stakeholders

Item 9 – Michelle Rowson confirmed that the updated Transfusion IT systems guidance document had been reviewed by the Inspectorate and that review comments would be provided outside of the meeting.

Action 10 – Michelle Rowson confirmed that David Churchward had provided the requested clarification with respect to data on traceability levels.

AOB – Dates for October meeting dates were agreed

AOB – Rationale for LD discard limits included as an agenda item for this meeting.

4. **Regulatory Update**
   Ian Rees gave an update on and key points of note were:

- The next Blood Competent Authority meeting on 3rd – 4th November 2014
- Review and revision to Blood Directive (BD) – essentially, there has been no progress. Some changes are being made to EU Tissues & Cells Directive (ECTCD) on import, temporary deferral of allogeneic after exposure to West Nile Virus ('28 days after leaving a risk area of locally acquired West Nile Virus transmission unless an individual Nucleic Acid Test (NAT) is negative').
- Good Practice – Andy Hopkins is in Strasbourg today to meet with Council of Europe's GTS group for maintenance / update on changes (e.g. GMP Chapter 1). Discussion on-going with the Commission on adoption and visibility on Commission website.
- Starting materials regulation for ATMPs - No issues for other medicines (blood products) which start under BD, long established and only BD possible. Classification for starting materials for ATMPs, as some are under EUTCD, and others under Blood Directive. The Commission is looking to facilitate innovation and supply
- Harmonised clinical evaluation of new 'products' for blood, tissues and organs - Commission recognise that there is no evaluation framework for new 'products' under Substances of Human Origin (SoHo) i.e. blood, tissues and organs. It is note that the EU SoHo legislation has no efficacy requirement, only quality and safety. Aware of increasing complexity of 'products' and procedures and want to assure their quality and safety. The Comission is keen to understand industry views and that if any protocols are put in place that they are 'light', streamlined, and allow for easy comparison and adoption.

5. **SABRE update**
Mike Dawe provided the following update on reporting trends.


SABRE October 2014 BCC.pdf

6. **Inspections Update**
Michelle Rowson reported that a new realigned structure has been created to bring the Inspectorate together as a cohesive team. Mark Birse will head the new team as Group Manager Inspections and reporting to Mark are four new Unit Managers. Two Expert Inspectors have been appointed to Unit Manager positions as part of the realignment process – Richard Andrews is the new Unit Manager Inspection Operations with line management responsibility for GMP and GPvP Inspection teams. Ian Rees is the new Unit Manager Inspection Strategy. Andrew Gray will assume responsibility in the interim period of the Unit Manager Inspection Operations with line management responsibility for GCP, GDP and GLP Inspection teams whilst this post is recruited. Recruitment for the post of Unit Manager Inspection Risk, Control & Governance is also on-going.


Inspectorate structure.pdf

Stephen Grayson provided the following update following a review of deficiencies and examples from Blood sites in 2013. To place the findings related to MHRA blood inspections in context with the GMP inspectorate's overall activity, certain pharma data has been provided within this presentation. The top two frequently encountered defect categories were '*Investigation of anomalies – CAPA*' and '*Investigation of anomalies*'. The presentation compared data for sites with critical and major findings including IAG referrals and Stephen Grayson briefly referenced the role of the Compliance Management Team (CMT). **Action – MHRA Inspectorate to present further information of the role and remit of CMT at the next BCC meeting.**


Inspection Findings 2013 with blood site s

Michelle Rowson reported that Stephen Grayson would be leaving the Agency in November 2014 and thanked him for the valuable contribution he had made to the Inspectorate, particularly through his involvement with the BCR process and supporting the BCC related projects. The committee members also offered their thanks and appreciation to Stephen.

7. **Rationale for LD discard limits**
Shelia MacLennan provide the following presentation to explain the rationale as to why units with > 1 x 10^6 leucocytes were not being discarded & the UK Services were routinely employing a discard limit of > 5 x 10^6

Concessionary Release Limits for Leu

The following post meeting response was provided by David Churchward:

The MHRA accepts the JPAC recommendation (September 2014; submitted to the Blood Consultative Committee meeting on 2 October 2014) regarding the interpretation of blood component leucocyte depletion limits stated in the Blood Safety and Quality regulations. It is noted that compliance with the limits stated in the Regulations is also dependent upon the use of a statistically valid sampling plan. It is noted that the UK blood component Quality Monitoring Group has developed guidelines on the implementation of statistical process monitoring to support the quality control testing of blood components. While the actual implementation of the statistical sampling plans may vary for different quality attributes, the approach proposed by the QM Group is acceptable in principle, and will be reviewed in practice during future inspections of UK blood establishments.

8. **SHOT update**
Paula Bolton-Maggs presented the following highlights from the Annual SHOT report 2013.

Sept 2014 SHOT update.pdf

9. **AOB**
Guidance for Transfusion IT systems – Chris Elliott asked for clarification on how the guidelines will be implemented and whether a gap analysis was required. **Action – MHRA Inspectorate and SABRE to review and confirm next steps with Chris Elliott.**

GMDP Inspectorate stakeholder questionnaire – Joan Jones requested feedback from the recent stakeholder questionnaire. Michelle Rowson reported that the feedback had been largely positive and opportunities for improvement were being reviewed by the Inspectorate management Team. **Action – MHRA Inspectorate to present further information on the stakeholder questionnaire at the next BCC meeting.**