Blood Consultative Committee (BCC) Meeting

6th February 2018, 12:30 to 16:00

MHRA Buckingham Palace Road G1

Draft Minutes

1. **Introductions and apologies for absence**
   The meeting was opened, and everyone was thanked for attending, new members were welcomed, and apologies were noted.

2. **Approval of Minutes of previous meeting held 1st November 2016**

2.1 Matters arising from minutes:

Item 7 – Collaborative working (standalone agenda item (agenda item 3)

Item 8a – Perfusion of organs for transplantation – proposed traceability model.

The BCC discussed a paper tabled by NHSBT relating to traceability requirements for perfusion of organs for transplantation.

Joint Professional Advisory Committee (JPAC) is interested in convening a working group to provide guidance on solid organ perfusion, including traceability considerations.

It is noted that the NHSBT paper considered issues other than traceability, and that for organs perfused following harvest, the traceability requirements were like those already published for blood dispatched with patients during inter-hospital transfer.

JPAC responded that a proposed manual flag to the hospital blood bank issuing blood for post-harvest organ perfusion may not have the ability to record the proposed information relating to blood requested specifically for this purpose.

It was agreed that MHRA would consult with HTA for their view on the traceability requirements and send a list of questions to NHSBT for consideration. MHRA would also wish to follow the JPAC process for developing their proposed guidance in this area.

- **Action: MHRA to liaise with HTA on traceability requirements, and send list of collated questions to NHSBT**

3. **Collaborative working:**

3.1 Update on collaborative working with other agencies

HTA/MHRA,
MHRA discussed their relationship with the Human Tissue Authority. The MHRA and HTA now has a formal agreement to share information on sites which hold both MHRA manufacturing authorisations and HTA processing licences. The two Agencies have a technical liaison group which meets regularly to discuss areas of mutual interest.

SABRE queried what opportunities there were for alignment between MHRA and UKAS due to a perceived doubling of effort. Areas could include agreeing common terminology and recognition of inspections.

Action: MHRA: Further explore links between MHRA and UKAS

3.2 - Results of BCC member survey,
MHRA presented feedback from a survey of BCC members, which was commissioned following the November 2016 BCC meeting to capture thoughts and ideas on how to develop a new meeting format and terms of reference for the BCC. Meaningful analysis of the results was limited given that 82% of the stakeholder organisations represented at the BCC did not take part in the survey. The response rate was in line with feedback that only a limited number of organisations actively participate in BCC meetings. The limited feedback did not provide any new suggestions on how to provide a forum for two-way discussion on the potential impact of future regulatory changes and to take forward strategic issues. MHRA concluded that for the BCC to evolve, MHRA need to understand the reasons why there is a lack of engagement from the wider membership before an effective meeting agenda and format could be adopted.

3.3 Proposal for BCC format and frequency,
MHRA proposed to the committee that the MHRAs preference is for an annual meeting, held in the first quarter of each calendar year. A more frequent meeting would require substantially more input from members in terms of topics for discussion. These would need to be submitted to MHRA with sufficient notice to make arrangements for an additional meeting.

3.4 On-line forum for blood stakeholders: Review and future use
MHRA presented a summary of the purpose of the forum and uptake since launch. The forum is actively used by few people. Committee members were asked to raise awareness of the forum, and encourage people to register. This could be achieved through discussion at regional transfusion groups, MHRA blogs and inspectors highlighting when inspecting. Various suggestions were offered to enhance the forum such as posting examples of good practice, questions about inspections, to trigger conversations. Users (and potential users) should be reassured that the forum is a 'safe space' for them to discuss topics, the fact it is hosted by the regulator should not affect this. It was suggested that the forum could incorporate input from patient groups which would be beneficial for laboratory staff to read and drive service improvement by improved visibility of the patient.

Action: MHRA to consider potential input to forum or other communications from patient groups.

3.5 Suggested ways of working and round table discussion e.g. task and finish working groups
Task and finish groups were considered a possibility; this approach was previously successful for example an IT guidance document was prepared this way.

3.6 Process for committee members to submit agenda items for BCC
MHRA will investigate what options are available to facilitate committee members (and potentially non-members) submitting agenda items for the BCC. This is likely to be an area on the blood forum or an email address.

<u>Action:</u> – MHRA: To implement a mechanism for reporting agenda items and communicate this to committee members.

Post meeting note: The email address bloodcc@mhra.gov.uk has now been set up for this purpose.

4. **<u>SABRE Update</u>**,

An update was presented on SABRE. This is the second full year where we have been collecting SABRE data under the new reporting process. Although unable to monitor trends, it has been possible to compare categories to last year. There has been an increase in reporting both SARs and SAE, but most of the increase in SAEs has come from Blood Establishments rather than hospitals. Most reports (98%) are still reported in the Human error category, and the majority of these are reported to be down to slips and lapses in individuals. This category may be a fair representation for some of those incidents, but it is noted that along with recent inspection findings, poor quality investigations and report writing may not have established the real root causes.

There has been a slight variation in the types of error reported. There have been decreases in Incorrect blood components issued, pre-transfusion testing errors and sample processing errors. There have been increases in component collection errors and data entry errors. Processes that can be easily defined and controlled by technology are therefore improving, but those which rely more on human interactions are not.

Future developments are a change of software from Lotus Notes to Appian will mean that SABRE will look different, but the functionality will be the same or improved. Links to the SHOT database will remain. There is a new Principal Haemovigilance Specialist will re-join the agency on 01/03/18 in a slightly different role to the one he left.

5. **<u>BCR process update</u>**

<u>2018/19 BCR forward look,</u>

MHRA provided an update on the BCR process. From 01 April 2018, HBBs will be provided with a letter to confirm that assessment has been completed, without indicating the outcome (i.e. inspection or no inspection). All inspections will be performed with a maximum of 7 days' notice.

It was explained that action is being taken because several MHRA hospital blood bank inspections during 2016 and 2017 identified good practice failures resulting in compliance management escalation, or regulatory action. Failures were often linked to lack of resources and/or failure of management oversight, and indicators suggest that organisations may reduce focus on regulatory compliance until an inspection notification is received. Performing inspections with a shortened notice period will encourage senior management to focus on maintaining compliance, rather than waiting until notified of an inspection date.

MHRA also notified the BCC of plans to publish the outcomes from hospital blood bank inspections. This will act as an educational tool for others, and further highlight the importance of on-going compliance.

2017/18 BCR process review and inspection trends,

MHRA presented the changes in the 2016/17 BCR process, the outcome and common issues identified in the BCR process. In 2017 MHRA has decided to change its post assessment communication to advise sites that they have been assessed. The graded compliance letters used in previous years have been withdrawn with all sites receiving the same letter. This decision supported a more dynamic risk-based approach and was in line with the communications for medicines which was issued in a recent MHRA blog. (https://mhrainspectorate.blog.gov.uk/2017/06/26/an-inspector-calls-part-1-gmp-short-notice-and-unannounced-inspections/).

MHRA also presented a summary of Major and Other deficiency groups identified at the Hospital Blood Bank inspections, with some examples.

Continuous improvement will be made on the Blood Compliance Report and the BCR process. The person who is responsible for completing the BCR should read the guidance notes prior to completing the BCR.

6. **Regulatory Update**,

MHRA gave an overview of the regulatory work which is currently being undertaken.

6.1 Review of the EUBD and EUTCD which is due to report end 2018
This work is reviewing both areas of legislation to see if they have met their original objectives (i.e. ensuring safety and quality) and whether they are fit for the future. There have been a series of open and inclusive engagements as set out in the European Commission's 'roadmap', MHRA has been involved in that process. The report is due to be published later in 2018, although there is no certainty on the outcome it is likely that both directives (and consequently their technical directives) will be revised. If that happens the process will most likely start in 2019.

6.2 Joint action on regulatory controls for new blood components and new tissue components which is due to start Q2 2018
MHRA have been requested, and has agreed, to participate in a European Commission project, termed a Joint Action, which is designed to support innovation in the fields of blood for transfusion and tissue and cells for transplant and infertility treatment. The title of this Joint Action is 'facilitatinG the Authorisation of Preparation Processes for blood, tissues and cells' (GAPP). The objective is to develop a common and proportionate approach to the assessment and, where needed, authorisation of preparation processes in blood establishments and tissues establishments.

MHRA's role in GAPP is restricted to blood components, working closely with JPAC and NHSBT, and are formal collaborating partners in this Joint Action. MHRA, JPAC and NHSBT's actions are restricted to work package 6, which is one of the ten sections in this Joint Action and is on the authorization of novel changes to blood components.

The authorisation of the production and supply of blood or tissue components does not currently exist in either the blood or tissues and cells legislation. However, within the UK, 'approval' of new components occurs through JPAC's development of guidelines for the UK Blood Transfusion Services and is collectively known as the Red Book. MHRA proposes to utilise JPAC's experience and which is informally used by many EU and international blood transfusion services.

GAPP is a 3-year project and will run alongside the review of the legislation on blood and tissues and cells (see above) which is likely to contain stronger legislative basis for authorisation of novel components.

6.3 Adoption of Good Practice Guide for Blood
The legislation to bring the changes into effect via an amendment to the BSQR (2017 No. 1320) will come into effect on 15th February 2018 - http://www.legislation.gov.uk/uksi/2017/1320/made/data.pdf

6.4 **Brexit**,
MHRA provided an update on preparations for leaving the EU. The Department of Health and Social Care (DHSC) has the policy lead for blood (and tissues) and is therefore working on this in conjunction with the Department for Exiting the European Union (DExEU). MHRA has been involved in meetings with DHSC and supplied information as needed. The work has focused on ensuring that following departure that there is day one operability which is to ensure that there is legal and operational continuity.

7. AOB

7.1 BCC member list – who are people representing?

A list was circulated at the meeting for attendees to record which organisations they represent. This will be used to update MHRA records to ensure the committee is representative of the sector. DHSC may also need to engage with blood stakeholders on Brexit issues; if so this list will be provided to DHSC.

7.2 Move to Canary Wharf

MHRA provided an update in relation to their office move. In mid-2018, MHRA will be moving from 151 Buckingham Palace Road to 10 South Colonnade, Canary Wharf, a new Government hub housing around 5700 civil and public servants. This location was chosen due to its good public transport connections and significantly lower cost comparative to other central London locations.

7.3 Contingency plans

MHRA reminded committee members of the importance of contingency planning, considering the recent collapse of large service provider to the health sector. Blood banks should understand their reliance on third parties for essential services, and consider how they would operate their services in the event of failure. Contingency and capacity planning is an area of increasing focus during inspections.

7.4 Manual back up system for LIMS

MHRA and The Welsh blood service briefly discussed the topic of arrangements for LIMS backup.

7.5 Merges occurring in pathology labs – at what point do hospitals let us know?

NTLMS queried when MHRA should be informed if pathology labs are merging. For most labs, this should be retrospectively reported as part of the BCR process. However, if the laboratory holds a Blood Establishment Authorisation this would need to be communicated proactively, as the Authorisation would need to be updated; this should be communicated using the Interim Compliance Report process.