Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Minutes

Blood Consultative Committee
3rd March 2020
MHRA 10 South Colonnade, Canary Wharf

1. Introduction and apologies for absence

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

2. Approval of Minutes of previous meeting held 5th February 2019, and actions arising.

The minutes of the meeting were approved.

Matters arising from minutes:

- 4.3 Blood Forum: MHRA to investigate whether there is existing unused functionality within the forum software to allow a daily/weekly digest emails to be sent, and if so to provide appropriate guidance.
  Update: Functionality is available but there are some technical issues with updates being sent to certain addresses when requested. These issues remain under investigation.

- 2.1 Collaborative working:
  Update: MHRA introduced the item with a reminder that MHRA had been in discussion with UKAS to identify any opportunities for collaborative working, but this work had been placed on hold as a result of preparations for EU Exit. Although the UK has now left the EU, work on the future relationship remains a priority, however an exploration of collaborative working remains on the future work plan. MHRA clarified that although terminology used by MHRA and UKAS is a perceived area of difference, in practice MHRA do not consider precise terminology to be important as long as it is defined and used consistently. UKTLC had raised a question of whether there was scope for CQC to review the link between HBBs and hospital executive teams; a representative from CQC was present at the meeting and noted the suggestion.

3. MHRA updates

MHRA staff changes since the last meeting were summarised:

- Chief Executive, Dr Ian Hudson, had retired and been replaced on an interim basis by Dr June Raine.
- Director of Devices, John Wilkinson had retired and been replaced on an interim basis by Graeme Tunbridge.
- Dr Andrew Gray had been permanently appointed as Head of Inspectorate.
- Richard Andrews (GMP/GDP Unit Manager) had left the Inspectorate, with recruitment ongoing for his replacement.
- Three blood inspectors (Kevin Page, Richard Parker and Stephen Grayson) planned to fully or partially retire during 2020.
- Two additional inspectors were in training (Ewan Norton, Senior GMDP Inspector and Julie Goodliff, GMDP Inspector).

4. Review of the role and membership of the Blood Consultative Committee

The committee discussed whether the current membership and attendance was representative of the sector and stakeholders. Although no specific gaps in representation were identified during the meeting, members were requested to submit any proposals for new members to the bloodcc mailbox. Several groups represented on the committee have patient groups and lay members. This provides an opportunity for the committee to consider input from a wide range of stakeholders.

Action: Committee members to notify MHRA of any groups that would be appropriate to participate in the committee to cover any gaps in representation. Proposals should be submitted to bloodcc@mhra.gov.uk including a rationale for inclusion.

It was identified that the MHRA website information for the committee (https://www.gov.uk/government/groups/blood-consultative-committee) required updating.

Action: MHRA to review and update website information about the committee

5. EU Exit update

DHSC presented an update on the Transition Period and the UK's negotiating approach to the future relationship.

MHRA confirmed that the Good Practice Guidelines for Blood Establishments will remain the primary standard against which inspections are performed; this guidance is issued by the Council of Europe of which the UK remains a member.

6. Agenda items submitted by committee members

Committee members had been invited to present a summary of the organisation they represent, and any current issues being faced. Updates were provided as follows:

Institute of Biomedical Science (IBMS): IBMS had noted an impact on service delivery due to the training burden on Senior BMS staff associated with high staff turnover.

Welsh Blood Service (WBS): An update was provided on the organisational development that had occurred as part of the All Wales Blood Service implementation since 2016 and on wider activities in relation to transplants etc.

United Kingdom Transfusion Laboratory Collaborative (UKTLC): The UKTLC 'Culture Survey' had been completed and there was a desire to run more surveys at a local level. Consideration was being given to re-run the survey in 2-3 years to identify changes. Communication across the TLM network was discussed, and a request was raised for any committee members who were in a position to provide admin support to the newly formed London South East Coast network.

Scottish National Blood Transfusion Service (SNBTS): Following opening of the Jack Copland Centre in December 2017 the organisation has been in a settling in period and this has now transitioned to business as usual at the Jack Copland Centre and for the rest of the organisation, with the normal level of projects and service improvements. In addition, the organisation had identified a number of additional challenges to be faced over the next 12 months.

Haemophilia Society: The society represents 30000 people with bleeding disorders, providing support and advocacy. Ongoing areas of focus included ensuring appropriate use of recombinant and plasma-derived products, the Infected Blood Enquiry, and women with bleeding disorders.

Serious Hazards of Transfusion (SHOT): The recommendations of the 2019 SHOT report were summarised (see https://www.shotuk.org/shot-reports/). Preparation was ongoing for the 2020 report.

NHS Blood and Transplant (NHSBT): A summary was provided of changes to the organisational operating model, which was felt to have delivered a better experience for donors and hospitals.

Northern Ireland Transfusion Laboratories: A summary was provided of planned changes to automation equipment and software including a future objective to implement a regional LIMS across the NIBTS and Hospital Blood Banks.

7. SABRE Update

A summary of SABRE data was provided. There had been no change in overall numbers of SAEs received. Storage errors had increased but errors in the 'Other' category and those attributed to slips and lapses had decreased.

The Haemovigilance Team Manager provided an update of his education and support work. Common issues identified were a lack of available capacity and knowledge to balance operational need with MHRA compliance, manufacturers not meeting a site's needs, and delays to SABRE investigations caused by investigations being taken over by Trust risk management departments and excluding those staff with knowledge of the event and of the processes, procedures, systems of the laboratory. This approach should be discouraged as investigations performed remotely are at a higher risk of drawing inappropriate conclusions, not identifying correct root cause and therefore not implementing effective CAPA.

8. BCR Process Update

The 2019/20 BCR cycle had considered 303 blood compliance reports and the BCR Assessment Team (BAT) had selected 25 laboratories for inspection based on risk. Of the inspections performed to date there had been two referrals to the Inspection Action Group (to consider the need for regulatory action), two referrals to the Compliance Management Team (for escalated case management and to direct the laboratory towards a state of compliance), and three 'Type 2' letters issued indicating that significant improvement was required. Deficiency trend data was shared from the inspections performed, covering the areas of Equipment and Materials, Non-conformance and Recall, Personnel and Organisation, and Documentation. A general finding was also noted of incomplete or overdue actions in relation to a previous inspection; any changes to commitments including agreed target dates must be communicated to the Inspector, and this had not always happened.

For the 2020/21 cycle a number of changes have been implemented to more accurately identify specific risks, to improve the clarity of guidance documents accompanying the BCR, and to improve the effectiveness of the Blood Facility declaration process.

Regarding the facility declarations, a suggestion was made by a member that an acknowledgement letter should be sent upon receipt. This will be considered for future implementation depending on the success of the most recent changes to improve reporting.

9. Regulatory Update:

9.1 Review of the EU Blood Directives (EUBD) and EU Tissues and Cells Directives (EUTCD)

The Commission held a conference on the Evaluation of the EU legislation on blood, tissues and cells in Brussels on 28 October. The evaluation found that the EU legislation has effectively helped increase safety and quality of blood, tissue and cell therapies. It also found that many of the current safety and quality requirements are outdated and it has been challenging to keep detailed technical provisions in pace with this rapidly changing sector. It also suggests that requirements for national oversight are not specific or adequately robust, leading to divergent approaches to oversight, reduced mutual trust and consequent barriers for exchange of, and access to, these therapies. The evaluation

highlights some concerns in terms of comprehensive protection of EU citizens and that the current EU legal framework does not keep up with the high level of innovation in a sector where innovation can facilitate patient access to treatments in an affordable manner.

In conclusion, the EU directives have substantially improved safety and quality of blood, tissues and cells in the EU. While public confidence in the sectors remains high, there are some gaps and shortcomings to address. The review stage will have to follow better regulation guidelines and the next Commission work will start soon. It was too early to speculate about what will need to be done and what mix of legislative and non-legislative instruments to be used.

9.2 Joint Action "facilitatinG the Authorisation of Preparation Processes for blood, tissues and cells (GAPP)"

This is a three-year project initiated by the National Institute of Health in Italy. The key objective of the Joint Action is to facilitate the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments for novel components.

The Joint Action is made up of 10 work packages. Just under half of them are housekeeping activities. The other work packages cover developing guidance, assessing quality, safety and clinical data, knowledge sharing and developing training courses.

MHRA together with its collaborating partners (JPAC and NHSBT) are leading for blood on work package 6, a technical Annex 1 on authorization changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package inserts). The Agence de la biomédecine has overall WP6 lead for blood, tissues and cells.

To date the working group has reviewed:

- An earlier VISTART Joint Action WP5 Questionnaire concerning blood
- UK Measures Chapter 8 of Guidelines for Blood Transfusion Services
- Annex IV and V of Directive 2004/33 which implements Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.
- The Council of Europe's Guide, the 19th Edition of "The Guide to the preparation, use and quality assurance of blood components" produced by the European Directorate for the Quality of Medicines & HealthCare's which extensively elaborates and extends these quality and safety requirements (criteria) for blood and blood components.

The critical characteristics for blood and blood components are well established unlike that for tissues and cells.

It has been agreed that The Guide to the preparation, use and quality assurance of blood components should be used as the main criteria data source for blood. This publication is commonly used by Member States as an established source for defined criteria and currently lists 36 components monographs which can be updated.

Work now starts on the Part II of WP6 developing guidance on the assessment of methods to demonstrate achievement/maintenance of the critical characteristics/properties for each category of SoHO, in particular where changes are proposed/implemented in one of the preparation steps. MHRA intends that this is work is supported by JPAC's Chapter 8 of Guidelines for Blood Transfusion Services which includes evaluation tables on:

- Evaluation of new red cell components for transfusion: recommended tests
- Evaluation of new platelet components for transfusion
- Evaluation of novel plasma components

10. AOB

Given the emerging issue of COVID-19, MHRA provided a summary of its actions to ensure it was prepared to fulfil its role as Competent Authority and to support health systems in the face of unexpected challenges. Committee members were asked to consider the potential impact of COVID-19 on items such as donor attendance, soft goods supply and staffing. Members were also asked to contact MHRA if they identify any additional concerns that may require input from the Competent Authority.