Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

BLOOD CONSULTATIVE COMMITTEE
DRAFT TERMS OF REFERENCE (Version 3)

1. The primary objectives of the Committee are:

   a) To advise and provide information to representatives of the national executive blood bodies, blood bank consultants, JPAC, SHOT, Haemophilia Society, Institute of Biomedical Sciences ,British society of Haematology, National Blood transfusion committees, CPA, the wider DH and Other Government Departments (OGDs) with respect to regulatory aspects of blood banks, blood establishments and blood processes.

   b) To provide a forum for consultation and two way discussion regarding proposed regulatory changes and provide a platform for stakeholders to discuss the potential impact of changes on their organisations.

   c) To provide a forum to raise and take forward actions on strategic issues.

2. At least one meeting will be held each year and will be co-ordinated by MHRA who will also provide the secretary. On-going communication will be maintained through alternative platforms such as the on-line discussion, Inspectorate Blogs and specialist sub-groups as appropriate.

3. The meeting will be attended by MHRA representatives from the GMP Inspectors, the Policy Group of Inspection and Standards Division, Medical Devices, and other MHRA personnel as appropriate for the scheduled business. Up to two representatives each from the interested national bodies, SHOT, hospital blood banks, the Haemophilia society, wider DH and OGDs will be invited to attend.

4. Items to be discussed may include:

   a) Regulatory and EU matters related to blood quality and safety.

   b) Feedback on the performance and operation of the haemovigilance system and the Licensing Office.

   c) Interpretation of the principles of GMP by the Competent Authority

   d) Forward look to give insight into the EU regulatory mindset, and have visibility of future changes, to prepare and remain compliant with regulations as they evolve

   e) Stakeholder ‘hot topics’

   f) Feedback from specialist sub-groups

   g) Compliance by blood banks and blood establishments (in general) with GMP and GDP (feedback from inspections)

h) Implementation of changes based upon newly emerging scientific evidence

5. A sub group will be set up under the auspices of the Blood Consultative Committee. This will review any detailed operational issues relating to SABRE. It will also discuss any technical points related to the reporting of serious adverse reactions and events. This will be a primary focus for discussions between the MHRA and SHOT.

6. The minutes of each meeting will be distributed to all representatives and published on the MHRA website.