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Guidance

Blood: authorisations and safety reporting

Licences and regulations for organisations that handle human blood or blood products and reporting adverse incidents with blood through SABRE.

From:
Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)

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The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the controls and authorisations that apply to blood establishments (BE) and controls that apply to hospital blood banks (HBB) and sites that collect, test and supply human blood or blood components intended for transfusion.

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> Information for hospital blood banks during the coronavirus (COVID-19) outbreak (https://www.gov.uk/guidance/information-for-hospital-blood-banks-during-the-coronavirus-covid-19-outbreak).

If the blood is intended for transfusion you need to comply with the UK's Blood Safety and Quality Regulations (http://www.legislation.gov.uk/uksi/2007/604/pdfs/uksi_20070604_en.pdf).

You are a BE and need to hold a blood establishment authorisation (BEA) if you:

- collect blood for the purpose of transfusion or manufacture of a medicinal product
- conduct donor tests
- process blood
- store or distribute blood

You will also need a BEA if you:

- carry out secondary processing of blood components, including
  - irradiation
  - cell washing
  - pack splitting
- collect blood or blood components for pre-deposit autologous transfusion (where the donor and recipient is the same person)
- import blood from a non-EU country (known as a 'third country')

You are a HBB and need to submit an annual blood compliance report if you are a unit within a hospital which:

- stores and distributes blood
- performs compatibility tests on blood and blood components exclusively for use in hospital facilities, including hospital-based transfusion activities

If you receive blood from a HBB for transfusion purposes but do not perform compatibility tests on site you are a 'facility'. Facilities do not have to submit a blood compliance report as long as there is service level agreement, or similar document, in place which clearly show that the HBB that supplies you is responsible for these functions.

If you're not sure which one you are contact MHRA by emailing gmpinspectorate@mhra.gov.uk or calling 020 3080 6000.

Blood establishments (BEs)

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- have a BEA
- be inspected by MHRA at least once every 2 years
- have a system for reporting any serious adverse blood reactions or events to MHRA (haemovigilance/SABRE)
- pay authorisation and haemovigilance fees each year and a further fee following an inspection

BE inspections

You will be inspected by MHRA when you first apply for your BEA.

After each inspection you will get a follow up letter describing the areas that need correction to get or keep your authorisation.

Complete a 2019 to 2020 BE compliance report

You will have to complete a BE compliance report before an inspection unless it is a triggered inspection, which are only notified at short notice.

Read the Compliance report guidance (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/780893/2019_Hospital_Blood_Bank_Compliance_Report_Guidance_Notes.doc) (MS Word Document, 2.01 MB)

For significant changes between inspections an Interim Compliance report (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/509215/BE_Interim_Compliance_Report.doc) (MS Word Document, 381 KB) is required to be submitted.

You should send your completed Pre-inspection compliance report (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/509216/BE_PreInspection_Compliance_Report.doc) (MS Word Document, 418 KB) to the email address given by the inspector. Hard copies of compliance reports will not be accepted.

Apply for a BEA

You must fill in a BEA application form (https://www.gov.uk/government/publications/blood-establishment-authorisation-application-form) and pay an application fee to MHRA. Send your completed application to plc@mhra.gov.uk.

The applicant at the blood establishment needs to sign the form.

The application will trigger an inspection. If you pass the inspection you will be

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your application.

To maintain your authorisation you will be inspected at least once every 2 years to ensure that you remain in compliance with the requirements of the legislation.

Make a change to a BEA (variation)

If your business or premises goes through any major change which will alter the authorised activities, sites or personnel, you must apply for a variation to your authorisation before making the change.

See variation forms for Blood Establishment Authorisations (https://www.gov.uk/government/publications/medicines-forms-to-make-a-variation-to-a-blood-establishment-authorisation)

Hospital blood banks (HBBs) and facilities

To operate as a HBB or facility you must:

- have a system for reporting any serious adverse blood reactions or events to MHRA (haemovigilance/SABRE)
- submit an annual compliance report and pay a compliance fee (only applied to HBB)
- pay a haemovigilance fee (unless you are a facility)

MHRA will inspect your organisation periodically depending on your organisation's level of risk, which is based on information in your compliance reports.

Blood Compliance Reports (BCR)

HBBs must send a blood compliance report to MHRA every year. This provides details about the activities you carry out, together with specific information relating to:

- processes
- procedures
- equipment
- personnel

The compliance report is used to assess your organisation for risk. The higher your risk rating the more likely your organisation is to be inspected.

Hospital blood banks must complete the compliance report and the declaration form. The majority of questions that need free-text responses have been removed, some sections are not available and some question numbers do not seem to be in order in

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Please read the 2023 Guidance on completing the Blood Compliance Report (https://www.gov.uk/government/publications/blood-bank-compliance-report-template).

The person responsible for signing the "Compliance Report completed by" section on the BCR Declaration Form must ensure all the questions are completed on the BCR, and the completed answers are true and accurate. Please submit Blood Compliance Report and Declaration Form (https://www.gov.uk/government/publications/blood-bank-compliance-report-template) to MHRA.

The compliance report template provides space for 10 external distribution sites; if more than 10 are supplied, additional sites can be reported including the same information using the 2023 Distribution sites addendum page.

Blood facilities do not need to complete a compliance report or declaration but must ensure that they have an agreement in place with the HBB that intends to supply them with blood components. The agreement should confirm the responsibility of the facility to comply with the BSQRs, with specific reference to storage (where relevant), traceability and reporting of serious adverse reactions and events.

Deadline for submission of reports is 30th April 2023

Closure of hospital blood banks

We now have a form to capture the closure of HBBs. At the point of HBB closure please fill in the Hospital Blood Bank Closure Form (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/964192/Hospital_Blood_Bank_Closure_Form_.docx) (MS Word Document, 847 KB) and submit the form to gmpinspectorate@mhra.gov.uk.

> We are offering guidance to hospital blood banks (HBBs) on flexible approaches to requirements (https://www.gov.uk/guidance/information-for-hospital-blood-banks-during-the-coronavirus-covid-19-outbreak) during the COVID-19 outbreak.

Fees

See fees for blood banks and other blood establishments (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees#blood-banks-and-other-blood-establishments-fees)

Make a payment to MHRA (https://www.gov.uk/guidance/make-a-payment-to-mhra)

Report a serious adverse event or reaction related to blood

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As a BE, HBB or facility you must report all serious adverse event and reactions related to blood to MHRA using SABRE. You will need to register with SABRE (https://aic.mhra.gov.uk/mda/sabresystem.nsf/Registration?Open) before you can report. SABRE does not replace your local reporting arrangements.

Report using SABRE (https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open)

If you have questions about SABRE email sabre@mhra.gov.uk

For access to the latest Serious Hazard of Transfusion (https://www.shotuk.org/shot-reports/) (SHOT) reports please visit their website (https://www.shotuk.org/shot-reports/).

Legislation and guidance

Guidelines for Blood Transfusion Services in the UK (http://www.transfusionguidelines.org.uk/red-book)

The Blood Safety and Quality (Amendment) (No. 2) Regulations 2005 - SI 2005/2898 (http://www.legislation.gov.uk/uksi/2005/2898/contents/made)

The Blood Safety and Quality (Amendment) Regulations 2006 No.2013 (http://www.legislation.gov.uk/uksi/2006/2013/contents/made)

The Blood Safety and Quality (Amendment) Regulations 2007 No. 604 (http://www.legislation.gov.uk/uksi/2007/604/pdfs/uksi_20070604_en.pdf)

The Blood Safety and Quality (Fees Amendment) Regulations 2008 No. 525 (http://www.legislation.gov.uk/uksi/2008/525/contents/made)

The Blood Safety and Quality (Fees Amendment) Regulations 2010 - SI 2010 No 554 (http://www.legislation.gov.uk/uksi/2010/554/contents/made)

The Blood Safety and Quality (Fees Amendments) Regulations 2009 - SI 2009 No 372 (http://www.legislation.gov.uk/uksi/2009/372/contents/made)

The Blood Safety and Quality Regulations -SI 2005/50 (http://www.legislation.gov.uk/uksi/2005/50/contents/made)

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 No. 941 (http://www.legislation.gov.uk/uksi/2008/941/pdfs/uksi_20080941_en.pdf)

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