EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (AMENDMENT) REGULATIONS 2006

2006 No. 2013

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Description

2.1. These regulations further amend the Blood Safety and Quality Regulations 2005 (SI 2005/50) ("the principal regulations") to make a number of changes to the provisions governing the operation of blood establishments (establishments which collect, process and test human blood and blood components) and hospital blood banks (hospital units which store, distribute, and perform compatibility tests on, blood and blood components for use in hospitals). These changes relate specifically to traceability requirements and notification of adverse reactions and events and introduce Community standards and specifications relating to a quality system for blood establishments.

2.2. The Regulations also make further provision to apply certain provisions relating to record keeping and traceability of blood and blood components to a new category of facility, defined as a hospital, another facility or service owned or managed by a health service body, a care home, an independent clinic, a manufacturer or a biomedical research institute. Lastly, they extend fee charging for "for-cause inspections i.e. inspections of facilities following reposts of serious adverse reactions or events" and haemovigilance to this new category of facilities, in line with the fees currently charged to blood banks and blood establishments.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None

4. Legislative Background

4.1. The principal Regulations were made under section 2(2) of the European Communities Act 1972 and transpose into UK law two European Directives (2002/98/EC and 2004/33/EC) relating to standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. The Secretary of State is responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. The Secretary of State for Health has agreed that MHRA (an executive agency of the Department of Health) should perform these functions.

4.2. This instrument is being made to implement two further Commission Directives ["2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events" and "2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards
Community standards and specifications relating to a quality system for blood establishments"] which impose further technical requirements as to traceability of blood and quality standards for blood. A Transposition Note is attached to this memorandum

4.3. Directive 2005/61/EC imposes certain requirements on "facilities" i.e. hospitals, and other NHS bodies, care homes, clinics, manufacturers of medicinal products and medical devices who use blood and blood components these requirements are transposed by the insertion of two new Regulations into the principal Regulations.

4.4. In line with existing requirements for hospital blood banks facilities (who do not make arrangements with a hospital blood bank that the hospital blood banks will report adverse incidents on the facility's behalf) will be charged a a fee in respect of Heamovigilence by MHRA. Heamovigilance is reporting to and monitoring of serious adverse reactions and events by the MHRA in order that potentially contaminated blood may be removed from the distribution chain. Facilities will also, on the same basis as for hospital blood banks for a "for cause" inspection, i.e. an inspection considered necessary by the MHRA following one or more reports of serious adverse incidents.

4.5. This instrument also amends certain provisions of the principal Regulations to ensure that its provisions extend to cover hospitals in Scotland and Northern Ireland.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The UK supports the Directives and has been instrumental in their Development and negotiation. Their content largely includes technical requirements relating to blood and blood components. In addition, much of it is already good practice in UK Blood Services and the NHS. The principal Regulations significantly improve the assurances available about the safety and quality of the blood supply.

7.2. The Department of Health consulted on the transposition of these two Directives by amending the Blood Safety and Quality Regulations 2005 (No. 50) between April and July 2006. The consultation was conducted with key stakeholders, including blood services, NHS Trusts and other health professionals' establishments where blood transfusion may have taken place. There were fourteen responses to the consultation. These indicated broad support for the proposed amendments as a means of improving blood safety and quality standards.

7.3. A formal consultation response will be published produced. The Department of health will also consider the production of guidance for blood establishments to help them implement the Regulations. This will supplement the good practice guidelines for the interpretation of Community standards and specifications, which the Commission is obliged to produce under Article 2(2). Any additional national guidance will have to wait until the EC guidance is produced.

7.4. MHRA support the charging for "for cause" inspection of a facility. Comments were received regarding the need to ensure adverse reporting is streamlined to avoid any double reporting and the content of the reports will need to be clear and avoid unnecessary bureaucracy.

8. Impact

8.1. A Regulatory Impact Assessment is attached to this memorandum.

8.2. The impact on the public sector is that NHS hospital blood banks, blood establishments and facilities will be charged annual fees to cover the operational costs to the MHRA of "for cause" inspections. The Regulations also introduce the new offences listed in this Explanatory Memorandum.

9. Contact

9.1. Any queries to: Mr William Connon at the Department of Health. Tel 020-7972-3912 or email: william.connon@dh.gsi.gov.uk

REGULATORY IMPACT ASSESSMENT

Title

1. The Blood Safety and Quality (Amendment) Regulations 2006

Purpose and intended effect of measure

2. To transpose two European Commission (EC) Directives relating to the safety and quality of blood and blood products into domestic law:

    - Commission Directive 2005/61/EC sets the format for notifying serious adverse reactions or events, defines the minimum data required and lays down specific technical requirements dealing with traceability and reporting that apply to blood establishments, hospital blood banks and 'Facilities' where transfusions take place.
    - Commission Directive 2005/62/EC sets out the standards and specifications for the quality systems in blood establishments.

Background

3. European Blood Safety Directive 2002/98/EC (the 'parent' Directive) sets standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Directive 2004/33/EC, sets technical requirements in support. The minimum standards set by those Directives apply throughout the European Union. The Blood Safety and Quality Regulations 2005 (SI 2005 No 50), which came into force on 8 February 2005 and were fully implemented on 8 November 2005, transposed those Directives into UK domestic law.

4. The implementation of minimum standards of blood safety and quality throughout the European Union will have three main effects:
    - It sets a comparable level of quality and safety throughout the blood transfusion chain (collection, testing, storage and distribution of whole blood and blood components) in all Member States.
    - Member States must enforce those minimum standards and establish structures for national inspection, training and accreditation in accordance with the principle of subsidiarity (Article 5 of the Treaty).
    - It makes all blood donations traceable from donor to patient i.e. from vein to vein.

5. Two further technical Directives, dealing with haemovigilance and quality systems were subsequently adopted as EU Directives 2005/61/EC and 2005/62/EC in September 2005. Although many of their quality requirements and reporting systems had been anticipated in the Blood Safety and Quality Regulations, amending legislation is required to ensure that they are fully incorporated in UK domestic law by 31 August 2006.

Risk assessment

6. The quality and safety of blood and blood products in the UK is already amongst the best in the world but their use, like most medical procedures, can never be free of risk. The implementation of SI 2005 (No50) further improved the safety and quality of the blood supply and the implementation of these further technical Directives will help assure that those high standards are maintained in the UK and other EU Member States.

7. Should it fail to comply with these Directives the UK risks automatic infraction proceedings.

Options

8. Two options have been identified:

    - Option 1 - Do nothing.
    - Option 2 - Implement the Directives by 31 August in accordance with the period set.

Benefits

9. The principal benefits of implementing these Directives are that they will:
    - help establish and maintain common technical standards and comparable quality systems that further improve blood safety and quality throughout the transfusion chain;
    - ensure that blood or blood components can be traced from donor to recipient ;
    - give UK citizens confidence in quality and standards of blood quality and safety in any Member State; and
    - ensure that comparable standards apply to any supplies imported from third countries or territories.

10. As there is also the future possibility of freedom of movement of blood and blood products within the European Union and wider imports from other countries and territories, the UK Government supports the establishment and enforcement of minimum quality and safety standards.

11. Option 1 is not considered feasible, as the UK would be subject to infraction proceedings if it fails to bring into force the laws Regulations and administrative provisions necessary to comply with these Directives by 31 August 2006 at the latest.

12. Option 2 is considered operationally feasible, will achieve the expected benefits and the proposed transposition time scale comply with the required implementation date.

Impact

13. As the main requirements of both Directives were already anticipated when SI 2005 (No 50) was transposed, their implementation is not expected to present additional operational difficulties or significant costs in the UK.

14. Vein to vein traceability is already a requirement of the current Regulations. Blood establishments and hospital blood banks are therefore required to develop and implement systems that allow for feed- back and information on the fate of each unit of blood or blood product issued and to maintain records for 30 years. This should enable them to satisfy the traceability requirements of Directive EC/2005/61.

15. SI 2005 (No 50) also requires blood establishments and hospital blood banks to report serious adverse events or reactions and the reporting system developed for this purpose by the Medicines and Healthcare products Regulatory Agency (MHRA) – which has been designated as the UK competent authority on behalf of the Secretary of State - allows them to do so electronically.

16. The MHRA reporting system also provides an automatic link to the voluntary Serious Hazards of Transfusion (SHOT) scheme, a voluntary system already operating in the UK. SHOT has wide support amongst those involved in blood transfusions, benefits from professional ownership and encourages wider reporting than required by regulation e.g. the reporting and recording of “near misses” in its database.

17. As Directive 2005/61/EC extends responsibility for reporting adverse reactions to ‘facilities where a transfusion takes place’, it will require that those ‘Facilities’ maintain records of transfusions and have procedures in place for notifying blood establishments of any adverse reactions observed in recipients. Although that adds to the administrative burden, such a reporting system is already established good practice and should be easily incorporated in the service level agreement with the establishment supplying blood or blood components.

18. The requirement to submit an annual report and to communicate such information on serious adverse reactions and events as might be required to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded to each other also adds minimally to the administrative burden placed on the Competent Authority.

19. The quality system standards and specifications set out in Directive 2005/62/EC will require blood establishments to review their quality systems and revise them where necessary to ensure compliance.

Cost

20. There could be some additional costs to Medicines and Healthcare products Regulatory Authority (MHRA) (as the Competent Authority) and to blood establishments, hospital blood banks and the 'Facilities' where a transfusion takes place arising out of the quality standards, administrative tasks and record keeping requirements. Those costs are not expected to be significant as the overall aims of both Directives are already covered by the existing legislation and the capacity for reporting has been included in the existing system. The cost to each organisations will vary depending on the extent to which its systems already comply.

21. It is not anticipated that the provisions of these Directives will result in significant additional inspection costs. However, the MHRA is obliged, under the terms of its Trading Fund Order, to recover the full costs of the services it provides and cross-subsidy is not permitted. The Blood Safety & Quality Regulations 2005 provide for MHRA to charge hospital blood banks fees for "for cause" inspections ranging from £759 (more than 2 hours, but no more than 1 day on site), £2024 (more than 1 day but less than 3 days on site) and £3795 (3 days or more on site).

22. The current fees charged by MHRA for non-routine "for cause" inspections to hospital blood banks and the annual haemovigilance fees currently charged to hospital blood banks, under the Blood safety & Quality Regulations, are shown in the table below. These are the fees that will be payable by facilities under the amending Regulations.

	Fee (£)
Non- regular inspection – inspector on site >2 hours, but NMT 1 day	759
Non- regular inspection – inspector on site >1 day, but <3 days	2024
Non- regular inspection – inspector on site 3 days or more	3795
Annual haemovigilance fee (in respect of cost to MHRA of the operation of a system for receiving and assessing reports of serious adverse events and reactions)	375 PA

N.B. In cases where a hospital blood bank also holds a blood establishment authorisation, the annual haemovigilance charge is £375.

23. Under the amending Regulations, "Facilities" would be charged the same fees should "for cause" inspection be necessary and they would be charged the haemovigilance fee, unless they had entered into a written arrangement with a hospital blood bank for the bank to carry out haemovigilance reporting on their behalf [(see regulation 14(b)]. The costs of "for cause" inspections for Facilities, which by their nature are reactive rather than scheduled routine

inspections are not possible to quantify; nor are the numbers of facilities that will end up paying the annual haemovigilance charge because they have not entered into agreements with hospital blood banks to do their SAR/SAE reporting.

24. The costs to facilities of maintaining traceability records and records of transfusions for 30 years will depend on the systems they use and the extent of their activities. W

Impact on small business

25. It is not anticipated that the requirements of these Directives will have any specific impact on small businesses.

Competition assessment

26. The market for the supply of human blood and blood products - including its collection, testing, processing, storage and distribution of human blood and blood components - has been studied by the National Audit Office (NAO). The specific requirements of these Directives will not increase existing barriers to entry and harmonisation of standards should ease the movement of blood and blood components within the European Community, whilst ensuring that imported blood or blood components meet the same safety and quality standards.

Issues of equity and fairness

27. It is not considered that implementing these Directives raises any issues of equity or fairness.

Enforcement and sanctions

28. The Regulations will be enforced by the Competent Authority through a system of licensing, inspection and compliance verification. Breaches will constitute an offence. Breaching these provisions would constitute an “either way offence” of 3 months/level 5 on summary conviction and 2 years/unlimited fine on indictment. The Secretary of State has the power of entry into a facility to investigate actual or suspected breaches of these obligations.

Monitoring and review

29. Directive 2002/98/EC requires yearly reports to the Commission and Directive 2005/61/EC that serious adverse events or reactions are notified annually. Either could lead to reviews of the Directive and as with all new

legislation the Competent Authority will keep its operation under constant review.

30. It is intended to streamline the reporting requirements of 2005/61/EC into the current (Directive 2002/98/EC) report and not to create a multiple reporting regime.

Consultation

31. A formal 12 week public consultation exercise was carried out between April and July 2006. The consultation included a partial RIA. The consultation was conducted with all the key stakeholders including blood services, NHS Trusts and other health professionals' establishments where blood transfusion may have taken place. A full list of Consultees can be found in Annex A.

32. There were fourteen responses to the consultation. These were from the National Assembly of Wales, National Blood Service Division of NHSBT (NHS Blood and Transplant), the Welsh Blood Service, the NHS Operational Impact Group, the Royal College of Pathologists, the Royal College of Physicians, the Joint UKBTS/NIBSC Professional Advisory Committee (JPAC), Gwent Community Health Council , the Board of Community Health Councils in Wales, the United Kingdom Accreditation Service (UKAS) and three NHS Trusts (Great Ormond Street Hospital for Children, QE Hospital Kings Lynn, Mayday University Hospital)

33. Most respondees commented on the recording systems, suggesting a preference for an electronic record-keeping process, but highlighted the associated resource and financial implication of doing so. Also the logistical consideration of evaluating adverse advents outside hospitals setting. Some felt it would be difficult to carry out such procedures in a reliable way.

34. The comments received have been reflected in this RIA where appropriate.

Implementation plan

35. The Department of health will examine the need for the production of national guidance for blood establishments to help them implement the Regulations. This will supplement the good practice guidelines for the interpretation of Community standards and specifications, which the Commission is obliged to produce under Article 2(2). Any additional national guidance will have to wait until the EC guidance is produced.

Post Implementation review

36. The Department, together with the MHRA will review, on a regular basis, the costs of operating systems for authorisation, inspection, compliance monitoring and haemovigilance under the Regulations.

Summary and recommendation

37. For the reasons outlined in section 4 it is recommended that these two technical Directives be transposed into domestic legislation in the UK. No significant associated costs are expected and the introduction of common technical and reporting standards across the EU should improve the already high standards of blood safety and quality in the UK, benefit our citizens requiring treatment abroad and facilitate the import and free movement of blood and blood products between Member States. For these reasons, the UK Government welcomes the Directives.

Declaration

I have read this Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed:*Caroline Flint*

Date: 18th July 2006

Minister of State for Public Health

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Annex A: List of Consultees

Scottish Executive
National Assembly of Wales
DHSS Northern Ireland
Ministry of Defence
National Blood Service
Scottish National Blood Transfusion Service
Welsh Blood Service
Northern Ireland Blood Transfusion Service
Medicines and Healthcare products Regulatory Agency
Clinical Pathology Accreditation Ltd
Serious Hazards of Transfusion team
The Patients Association
Haemophilia Society
The Primary Immunodeficiency Association
National Transfusion Committee (including blood bank managers, consultant haematologists, surgeons, transfusion nurses , patient's representatives
Private Sector – IHA, BUPA, Nuffield Hospitals
Royal College of pathologists
Royal College of physicians
Royal College of surgeons
Royal College of nursing
Royal College of general practitioners
British Blood Transfusion Society
Guild of Healthcare Pharmacists
British Committee for Standards in Haematology
Joint UKBTS/NIBSC Professional Advisory Committee
NHS Trusts (via chief executives bulletin)
Nurses (via CNO bulletin).
Other Health professionals (via Allied health professionals bulletin)

Transposition Note for Blood Safety and Quality Regulations 2006

Commission Directive 2005/61/EC of 30th September 2005, implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events,			
Commission Directive 2005/61/EC of 30th September 2005, implementing Directive 2002/98?RC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments			
Article	Objectives	Implementation	Responsibility
1	To provide definitions of terms	.S.I. 2005/50 (the "principal Regulations") implements Commission Directive 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishment. And Commission Directive 2004/33/EC implementing Directive 2002/98/EC as regards certain technical standards for blood and blood components. These regulations amend S.I. 2005/50 to implement Commission Directive 2005/61/EC and Commission Directive 2005/62?EC Regulation 2 amends regulation 2 of the principal Regulations to incorporate the relevant definitions.	Regulations made by Secretary of State
2	ensures the traceability of blood and blood components through accurate identification procedures, record maintenance and appropriate labelling throughout the processing stages. Every blood establishment must have a unique identifier for each donor, unit of blood collected and each blood component prepared.	Regulations 5(2) and 6(1) amend the principal Regulations to implement Article 2.1 Regulations5(4) and 6(2)(f) amend the principal Regulations to implement Article 2.2 Regulations 5(5) and 6(2) amend the principal Regulations to implement Article 2.3 Regulation 7 inserts new regulation 12A into the principal Regulations to implement Article 2.4 Regulation 8 (1)(d) of the principal Regulations requires that each blood establishment label each unit of blood with the name of the producing blood establishment, as the name of each blood establishment is unique it is not considered that Article 5.5 requires further implementation Regulation 5(2) (d) requires a blood establishment to have a system in place,	The Medicines and Healthcare products Regulatory Authority (MHRA) (an Executive Agency of the Department of Health) will discharge the enforcement obligations of the Secretary of State who is designated the competent authority for the purpose of the se Regulations. As the MHRA does not have a separate legal personality, therefore the Regulations refer throughout to Secretary of State. Blood establishments and hospital blood banks are responsible for ensuring compliance with the requirements placed on them by the regulations

		which will uniquely identify each donor, blood unit and blood component and the facility to which the unit or component has been delivered. Regulation 6 (2) (f) requires that blood banks can trace blood components to their final destination including where the blood component has been transferred to another facility. Regulation 6 (3) requires that blood issued by a bank in a hospital, for transfusion, was issued to the intended recipient, or if not transfused, can verify the final disposal of the unit of blood. Regulation 7 requires that facilities have records in place for each unit of blood recording its use and final destination.	
3	Requires that blood banks and establishments have procedures in place to verify that every unit has been transfused to the correct recipient or if not transfused, disposed of properly.	Regulation 5(6) and 6(3) amend the principal Regulations to place this obligation on blood establishments and blood banks	MHRA on behalf of the Secretary of State Blood establishments and hospital blood banks are responsible for ensuring compliance with the requirements placed on them by the regulations
4	States that blood establishments, blood banks and facilities retain data on traceability for at least 30 years	Regulations 5, 6 and 7 of the amendment regulations amend the principal Regulations to impose this requirement on blood establishments, hospital blood banks and facilities and Part A and B of Part 6 to the Schedule of the principal regulations (the Blood Safety and Quality Regulations 2005 SI 2005/50) set out the required data set.	MHRA on behalf of the Secretary of State blood establishments, hospital blood banks and reporting establishments are responsible for ensuring compliance with the requirements placed on them by the regulations
5	Requires that those facilities where transfusion occurs (reporting establishments) have procedures in place to retain the record of transfusions and to notify blood establishments of any serious adverse reactions in recipients during or after transfusion, which may have been attributable to the quality, or safety of blood and blood components. They must also communicate all such reactions to the competent authority in the format set out in Annex II of the Directive.	Regulation 7 inserts a new regulation 12B into the principal Regulations which requires that reporting establishments comply with these requirements.	MHRA on behalf of the Secretary of State Reporting establishments are responsible for ensuring compliance with the requirements placed on them by the regulations
6	Blood establishments and blood banks are required to have procedures in place to retain the record of any serious adverse events, which may affect the quality, or safety of blood and blood components. Reporting establishments are	Regulation 4 states that blood establishments must retain records of serious adverse events, which may affect the quality, or safety of blood and blood components are retained for at least 15 years. Regulation 6 states that blood banks must retain this data for 15 years ref.	MHRA on behalf of the Secretary of State blood establishments, hospital blood banks and reporting establishment, are responsible for ensuring compliance with the requirements placed on them by the

	required to report and evaluate serious adverse events to the Secretary of State and to complete and send to the Secretary of State on an annual basis a complete report of all serious adverse events.	Regulation 7 inserts a new regulation 12B into the principal Regulations which requires that reporting establishments comply with these requirements.	regulations
7	Requires that for imports of blood and blood components from third countries equivalent systems are in place in place for traceability and notification to that provided for in Articles 2(2) to 6 of this Directive.	Regulation 3 amends Regulation 3 of the principle Regulations to provide that only blood establishments and manufacturers of medicinal products and medical devices may import blood and blood components from third countries. Where a blood establishment imports blood from a third country it is required to apply the same traceability systems to that blood as to blood which it has itself collected. Manufacturers do not transfuse blood but, as facilities, are required to keep records of the final destination of blood and blood components used by them (whether used in the manufacture of medicinal products or medical devices or discarded).In connection with the manufacture of medicinal products, and medical devices, manufacturers are subject the requirements of Directive 2001/83/EC and Directive [ ] respectively.	MHRA on behalf of the Secretary of State Blood establishments and manufacturers are responsible for ensuring compliance with the requirements placed on them by the regulations
8	Requires that an annual report is sent to the Commission by 30 June of the year following year, on notification of serious adverse reactions and events received by the competent authority	Does not require transposition the Secretary of sate is responsible for sending the reports	MHRA on behalf of the Secretary of State
9	States that competent authorities communicate with each other on appropriate information regarding serious adverse reactions and events.	Regulation 11 requires that the Secretary of State communicates appropriate information regarding serious adverse reactions and events to the. Competent authorities of other member States	MHRA on behalf of the Secretary of State
10	Requires that necessary regulations and administrative provisions be put in place by 31 August 2006 at the latest.	.S.I. 2005/50 implements this requirement and will come into force on 31 August 2006.	Regulations made by Secretary of State
Annex 1	Lists traceability data which must be retained by blood establishments, hospitals blood banks and facilities	The Regulations insert a new Part 6 into the Schedule to the principal regulations which transposed these requirements	MHRA on behalf of the Secretary of State Blood establishment, hospital blood banks and facilities are responsible for ensuring compliance with the requirements placed on them by the regulations
Annex 2-3	Sets out the formats for reports of serious adverse reactions and events	The Regulations insert new Parts 7 and 8 into the Schedule to the principal regulations which transposed these requirements	MHRA on behalf of the Secretary of State Blood establishment,

			hospital blood banks and facilities are responsible for ensuring compliance with the requirements placed on them by the regulations

Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.			
Article	Objectives	Implementation	Responsibility
Article 2 and the Annex	Sets out specific technical requirements – including standards and specifications - with regard to quality systems for blood establishments (and for blood or blood components imported from third countries) and determines common definitions for technical terminology in order to ensure consistent implementation	Regulation 4 and 6 amend the principal Regulations to implement the requirements of this Directive by providing that blood establishments, and insofar as applicable to their activities hospital blood banks shall ensure that their quality systems comply with the requirements set out in the Annex. Regulation 13 implements Article 2.3 by requiring that blood establishments and manufacturers of medicinal products and medical devices must ensure that any blood or blood components imported by them from a third country have been prepared to equivalent standards to those set out in the Annex. .	Blood establishments, hospital blood banks and manufacturers of medicinal products and medical devices who import blood and blood components from a outside the EU, the MHRA, acting on behalf of the Secretary of State as competent authority in respect of blood and blood components, medicinal products and medical devices will inspect to ensure compliance.