WQ.268/2019

WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES
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ANSWER TO BE TABLED ON TUESDAY 18th JUNE 2019

Question

What steps is the Minister's Department taking to ensure that contaminated blood is not donated to patients and, in particular, what changes to procedures in this area, if any, are being considered in light of the Infected Blood Inquiry being undertaken in the United Kingdom?

Answer

The matters before the UK Infected Blood Inquiry are primarily *historic* ones relating to concerns over the historic safety of the UK blood supply prior to 1992. The issues relate to an era in which neither HIV virus nor Hepatitis C virus had yet been discovered and a time when tests for these infections in donor blood had yet to be devised.

The relevant incremental changes in Jersey designed to safeguard the quality of the local Blood Supply have not waited until now for action, but have been securely in place for many years. The Jersey Blood Service (JBS) has deployed new state-of-the-art techniques to protect the Jersey blood supply as soon as those techniques have become available, both before 1992 and since.

The JBS continues to be compliant with a very extensive list of blood safety procedures, protocols and regulations that for the sake of brevity are listed separately in the Appendix attached.

A rigorous external assessment of the JBS was undertaken in July 2018 by inspectors working for the UK Medicines and Healthcare products Regulatory Agency (MHRA). Their inspection report on the JBS was very positive. That evidence plus professional advice from the Chief Pharmacist informed a Ministerial Decision in October 2018 to re-license the JBS for a further 3 years within the framework of the Medicines (Jersey) Law 1995.

I am grateful to the Island's blood donors whose efforts and loyalty continue to allow the Island to be more than 95% self-sufficient in the provision of blood packs for Island patients. I am also grateful to the specialist scientific staff at the General Hospital who have been judged to have such high quality standards in this endeavour that they match the standards of much larger organisations including MHRA-regulated multinational pharmaceutical companies.

APPENDIX

In order to manufacture blood packs for transfusion to patients, the Jersey Blood Service (JBS) is required to be licensed under the Medicines (Jersey) Law 1995. That licence is issued by the Health Minister provided that the Minister is satisfied, based on professional advice, that the procedures and quality management system (QMS) of the JBS meet EU/UK standards. These are the same standards that the MHRA as the statutory UK regulator applies to the Blood Centres of the UK National Health Service Blood and Tissue (NHSBT) service and to major pharmaceutical companies.

The EU, UK & Jersey Statutory Regulations

Medicines (Jersey) Law 1995

EU Directive 2002/98/EC – Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood components.

Council of Europe Guide to the preparation, use and quality assurance of Blood Components (2004)

UK Statutory Instrument 2005/50 – The Blood Safety and Quality Regulations 2005

Guidelines for the Blood Transfusion Services in the United Kingdom 2013 8th Edition (Red Book)

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017 (Orange Guide)

Quality Management system (QMS)

The Jersey Blood Donor Service has evolved an appropriate QMS to maximise blood safety and to comply with the relevant regulations and best practices in transfusion medicine, including the principles of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP). Dedicated IT software controls donor selection and each step of the blood pack production process.

The Donor Service QMS covers:-

i) Initial criteria for accepting, re-accepting and barring candidate Jersey blood donors
ii) Quarantining of blood packs post-donation, pending processing and quality assurance
iii) Rigorous testing of each blood donation
iv) Processing of blood packs post-donation to reduce the risk of vCJD* infection
v) Discarding all quarantined blood packs that fail any part of the Quality specification

Pre-donation Jersey Blood Donor medical screening and exclusion

Prospective blood donors are assessed against current NHSBT Medical Assessment of Blood Donors guidance. A proportion of candidate blood donors is barred from donating due to concurrent medical conditions, concurrent medication or personal circumstances associated with higher risk of transfusion-transmitted infection including intravenous drug use.

Prospective blood donors with a foreign travel history within the past year are additionally assessed against the NHSBT geographical index for blood donor travel exclusions. These exclusions apply for appropriate periods of time after foreign travel to minimise the risk of transferring to patients transfusion-related illnesses acquired abroad such as Malaria, Trypanosomiasis, and/or viruses including Chikungunya, West Nile or Zika.

Laboratory testing of quarantined Jersey Donor Blood Packs

Routine Hepatitis B testing of Jersey blood donors in place since the 1970s
Routine Syphilis testing of Jersey blood donors in place since the 1970s

Routine HIV testing for Jersey blood donors in place since 1986
Routine Hepatitis C testing for Jersey blood donors in place since 1992
Routine plasma-depletion of Jersey blood packs since 1998 - as a vCJD* risk reduction step
Routine white cell depletion of Jersey blood packs around 2003 - as a vCJD* risk reduction step
Routine testing of donors for atypical red cell alloantibodies
Manufacturing quality assurance – residual white cell counts following leuco-depletion filtration
Manufacturing quality assurance – testing on blood pack volume and red blood cell content

(*) vCJD = Variant Creutzfeldt-Jakob Disease as the human disease linked to the infectious prion agent found in cattle as Bovine Spongioform Encephalopathy (BSE)