# EXPLANATORY MEMORANDUM TO

# THE BLOOD SAFETY AND QUALITY (AMENDMENT) REGULATIONS 2017

# 2017 No. 1320

## 1. Introduction

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

## 2. Purpose of the instrument

2.1 This instrument implements European Commission Directive (EU) 2016/1214 which amends Commission Directive 2005/62/EC. The European Commission Directive (EU) 2016/1214 requires Member States to ensure that blood establishments and blood banks use good practice guidelines to interpret the standards and specifications set out in Commission Directive 2005/62/EC and take into account the Good Practice Guidelines.

## 3. Matters of special interest to Parliament

***Matters of special interest to the Joint Committee on Statutory Instruments***

3.1 None.

***Other matters of interest to the House of Commons***

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

## 4. Legislative Context

4.1 This instrument implements European Commission Directive (EU) 2016/1214. This is being implemented by making an amendment to the Blood Safety and Quality Regulations 2005 (SI 2005/50).

## 5. Extent and Territorial Application

5.1 The territorial extent of this instrument is the United Kingdom

5.2 The territorial application of this instrument is to 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

***What is being done and why***

7.1 Commission Directive 2005/62/EC requires Member States to ensure that quality systems are in place in all blood establishments and blood banks, and that these organisations comply with the standards and specifications set out in the Directive.

7.2 Commission Directive (EU) 2016/1214 amends this Directive and requires Member States to ensure that blood establishments use good practice guidelines to interpret these standards and specifications and take into account the Good Practice Guidelines jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe.

7.3 National experts, including Medicines and Healthcare products Regulatory Agency (MHRA), were involved in the drafting of the new Good Practice Guidelines and this included consulting with UK blood establishments and blood banks.

7.4 Currently UK blood establishments and blood banks use the EU Good Manufacturing Practice (GMP) guidelines originally written to apply to the pharmaceutical industry. The new Good Practice Guidelines uses the relevant parts of the EU GMP guidelines but with language more appropriate to blood establishments and blood banks. The quality system standards that MHRA inspect for compliance with are essentially unchanged but the publication of specific good practice guidelines, the Good Practice Guidelines, for blood establishments and blood banks should aid these organisations in understanding and implementation of those standards.

7.5 On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. The government respected the result and triggered Article 50 of the Treaty on European Union on 29th March 2017 to begin the process of exit. The UK's decision to leave the EU may have an impact on this legislation, along with other legislation in this area, though the extent to which it is affected will be determined by the outcome of the negotiations. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation.

***Consolidation***

7.6 The Department, at present, does not intend to consolidate the Blood Safety and Quality Regulations 2005.

## 8. Consultation outcome

8.1 The European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM) consulted on the Good Practice Guidelines prior to their adoption.

8.2 MHRA engaged with UK blood services (blood establishments and blood banks) through its Consultative Committee on Blood and with the Council of Europe Experts working group (GTS) which is comprised of members from the UK blood services and from the EEA and includes non EEA representatives from the US, New Zealand and Australia. The GTS group developed the Good Practice Guidelines. As MHRA engaged UK blood services during the development of the Good Practice Guidelines it was not considered necessary to provide further consultation ahead of implementation of the regulations.

8.3 MHRA inspect UK blood services. The quality system standards that MHRA inspect for compliance with are essentially unchanged by the Good Practice Guidelines.

## 9. Guidance

9.1 MHRA regularly engage with blood services across the UK through inspection. MHRA will contact the UK blood services again ahead of the instrument coming into force.

9.2 The Good Practice Guidelines can be found at: https://www.edqm.eu/sites/default/files/goodpracticeguidelines-19th_edition_guide_preparation_use_qa_blood_components-december2016.pdf

## 10. Impact

10.1 The impact on business, charities or voluntary bodies is minimal as the Directive does not require a change in practice.

10.2 The impact on the public sector is minimal as the Directive does not require a change in practice.

10.3 An Impact Assessment has not been prepared for this instrument.

## 11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses. However, as the Directive does not require a change in practice the impact on small businesses is minimal.

## 12. Monitoring and review

12.1 A review provision is not appropriate in this case.

## 13. Contact

13.1 Donna McInnes at the Department of Health Email: Donna.McInnes@dh.gsi.gov.uk can answer any queries regarding the instrument.