Memorandum of understanding between the Care Quality Commission (CQC) and the Medicines and Healthcare products Regulatory Agency (MHRA)

Introduction

This Memorandum Understanding (MoU) sets out the framework to support the working relationship between the Care Quality Commission (CQC) and Medicines and Healthcare products Regulatory Agency (MHRA).

This working relationship is part of the maintenance of an effective regulatory system for health and adult social care in England, which promotes patient safety and high quality care.

This document is not a legal agreement, and does not create legally binding rights or obligations; its purpose is to define the joint agreement between the two organisations and to indicate a common line of action.

Roles and Responsibilities

The Care Quality Commission

The CQC is the independent regulator of health and social care services in England. It also monitors the use of the Mental Health Act 1983 and protects the interests of people whose rights are restricted under that Act.

The CQC was established by the Health and Social Care Act 2008. Its main powers and responsibilities are provided under that Act, the Health and Social Care Act 2012, the Mental Health Act 1983, the Mental Capacity Act 2005, the Health and Safety at Work Act 1974, and regulations under those Acts.

CQC makes sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

To do this, CQC:

- Registers providers and managers, a process which checks that these persons can meet a number of legal requirements including fundamental standards of quality and safety

- Monitors registered services drawing on data, evidence and information, including feedback from service users and their families
- Performs provider inspections drawing on expert advice and, publishes findings
- Takes action to protect service users
- Speaks with an independent voice, publishing regional and national views of the major quality issues in health and social care.

The Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health and was established on 1 April 2003. The Agency has three centres:

- The Clinical Practice Research Datalink (CPRD) - a data research service that aims to improve public health by using anonymised NHS clinical data
- The National Institute for Biological Standards and Control (NIBSC) - a global leader in the standardisation and control of biological medicines
- The Medicines and Healthcare products Regulatory Agency (MHRA) regulatory centre - the UK's regulator of medicines, medical devices and blood components for transfusion. The regulatory centre is responsible for: ensuring their safety, quality and efficacy/performance; supporting innovation and new products being developed safely for the benefit of public health; monitoring the safety of medicines devices and blood; and, ensuring secure supply in globalised industries.

The MHRA is the UK Competent Authority under relevant EU Directives for medicinal products, medical devices and for blood and blood components.

The MHRA's objectives are to:

- Safeguard public health through our primary role in ensuring that the products we regulate meet required standards of safety, quality and efficacy;
- Carry out our communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public;
- Support research, ensuring through the application of better regulation principles that regulation does not stifle innovation;
- Influence the shape of the future regulatory framework through use of our effective European and international relationships; and
- Run an organisation with a skilled and equipped workforce that is fit for the future.

The MHRA's objectives are achieved through:

- Authorising medicines before they can be marketed, taking both their safety and efficacy into account;
- Ensuring clinical trials meet robust standards and safeguard the interests of patients;
- Inspecting the quality of medicines as manufactured and distributed;
- Overseeing UK Notified Bodies that audit medical device manufacturers;
- Encouraging the reporting of suspected problems with both medicines and devices and investigating reports, including taking action where necessary; and
- Investigating and prosecuting where necessary, cases of non-compliance.

Principles

CQC and MHRA acknowledge their respective statutory and non-statutory responsibilities, and will take these into account when working together.

As part of the activities undertaken as part of this agreement, other agreements (for example, information sharing agreements, or joint working protocols) may be established. Such agreements will exist separately to this agreement.

In implementing this agreement, the CQC and the MHRA are aware of and in agreement to the following principles, which support our focus on the safe care and treatment delivered to patients in England:

- Addressing overlaps and gaps in the regulatory framework and responsibilities
- Cooperating openly and transparently with the other organisation
- Respecting each other's independent status
- Using resources and intelligence effectively and efficiently

Joint priorities and areas of work

Information sharing

All exchanges of information will be lawful and proportionate. All arrangements for exchange of information set out in this MOU and any supplementary agreements will take account of and comply with the Data Protection Act 1998, section 76 of the Health and Social Care Act 2008, the Clinical Trials Directive (Directive 2001/20/EC), and any CQC and MHRA codes of practice, frameworks or other policies relating to personal data .

Subject to the above, both organisations are committed to the more effective use of information to support regulation. If either organisation receives information which:

- indicates a concern about the health and wellbeing of the public, particularly in relation to the safety of health and care services, or the use of medicines, devices or blood
- is relevant to the delivery of the other organisation's functions or
- would benefit from coordinated multi-agency response

then this information will be shared in confidence with the named contact in the other organisation at the earliest possible opportunity.

Communications

Each organisation will endeavour to make the other aware of planned public announcements on issues relevant to that organisation. This may be challenging in some circumstances, for example, where urgent enforcement action is required. In all situations, information sharing will be subject to relevant statutory requirements, and any organisational codes of practice or policies as detailed above (under *Information sharing*).

CQC and MHRA commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations.

Both CQC and MHRA are subject to the Freedom of Information Act 2000. If one organisation receives a request for information that originated from the other the receiving organisation will discuss the request with the other before responding.

Key contacts

Both organisations share a concern for the quality and safety of health and care delivered to patients, and recognise that development of new models of health and care delivery requires closer collaboration between the two organisations, especially where geographic boundaries are blurred, for example online.

To support effective and timely contact, details of key contacts within CQC and the MHRA are contained in Annexe A. These will be updated as needed by agreement between the named persons responsible for MOU management.

Governance

The effectiveness of the working relationship between CQC and the MHRA will be supported by regular contact, both formally and informally.

There will be an annual meeting between Chief Executives to discuss strategic and operational concerns relevant to both organisations. In addition, there shall be meetings at least twice a year between strategy and policy colleagues (see Annexe A) to discuss strategic, policy and operational issues of interest to both

organisations. Relevant operational colleagues from CQC and MHRA will attend these meetings as necessary depending on the issues under discussion.

When needed, support to make contact between CQC and the MHRA may be sought from the MoU contacts, named in Annexe A.

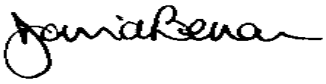
Any disagreement between the CQC and MHRA will normally be resolved at working level. If that is not possible, an issue may be brought to the attention of the MoU managers identified in Annexe A who may then escalate it as appropriate within the two organisations to reach a mutually satisfactory resolution.

Duration and review

Both organisations have identified a person responsible for the management of this MoU in Annexe A. They will liaise as required to ensure this MoU is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.

This agreement will be reviewed annually by the named persons responsible for MoU management.

This MoU is not time-limited and will continue to have effect until the principles described need to be altered or cease to be relevant. The MoU may be reviewed more urgently at any time at the request of either party.

Signed for and on behalf of:		**Signed for and of behalf of:**	
CQC		**MHRA**	
Signed		**Signed**	
Name	David Behan	**Name**	Ian Hudson
Title	Chief Executive	**Title**	Chief Executive
Date	25 September 2017	**Date**	26 September 2017

Annexe A

Care Quality Commission	**Medicines and Healthcare Products Regulatory Agency**
151 Buckingham Palace Road London SW1W 9SZ Tel: 03000 616161	151 Buckingham Palace Road London SW1W 9SZ Tel: 020 3080 6000

Named contacts for the CQC and MHRA

Chief Executives	
David Behan Chief Executive david.behan@cqc.org.uk	Dr Ian Hudson Chief Executive Ian.hudson@mhra.gov.uk
Senior Responsible Officials	
Sarah Billington Head of Medicines Optimisation sarah.billington@cqc.org.uk	Jonathan Mogford Director of Policy Jonathan.Mogford@mhra.gov.uk 020 3080 6600
MoU Management	
Grahame Whitfield Strategy Manager grahame.whitfield@cqc.org.uk	Paul McCormack Head of Strategic Partnerships Paul.mccormack@mhra.gov.uk 020 3080 6965
Communications & Media	
Tom Coales Head of Parliamentary & Stakeholder Engagement thomas.coales@cqc.org.uk Paul Cooney Media Manager paul.cooney@cqc.org.uk	Malcom Evans Head of Patient, Public and Stakeholder Engagement Malcolm.evans@mhra.gov.uk 020 3080 7016 Jennifer Kyne Head of News, Digital and Content Jennifer.kyne@mhra.gov.uk 020 3080 6638

Annexe A (contd)

<table>
<tr><th colspan="2">Other contacts</th><th>Notes</th></tr>
<tr><td>Ana Da Costa
Analyst Team Leader
(CAS organisations contact)
ana.dacosta@cqc.org.uk</td><td>Ben Scott
Patient Safety & Vigilance Strategy Delivery Manager, Communications Division
Ben.Scott@mhra.gov.uk
020 3080 6725</td><td>Data shared between CQC and CAS to ensure newly registered entities receive alerts.</td></tr>
<tr><td rowspan="3">Sarah Billington
Head of Medicines Optimisation
(Medicines contact)
sarah.billington@cqc.org.uk

Janet Ortega
Head of Integrated Care (Inspection/operational contact)
janet.ortega@cqc.org.uk

Ana Shaer-Levitt
Analyst Team leader
(Intelligence Contact)
ana.shaer-levitt@cqc.org.uk</td><td>Sarah Morgan
Group Manager, Vigilance & Risk Management of Medicines Division
Sarah.morgan@mhra.gov.uk
020 3080 6763</td><td>Medicines Safety issues</td></tr>
<tr><td>Janine Jolly
Devices Safety Unit Manager, Devices Division
Janine.jolly@mhra.gov.uk
or
aic@mhra.gov.uk
020 3080 6690</td><td>Medical Devices safety issues</td></tr>
<tr><td>Lynda Scammell
Relationship Manager / Senior Policy Manager, Inspection, Enforcement & Standards Division
Lynda.scammell@mhra.gov.uk
020 3080 6665</td><td>Enforcement issues</td></tr>
</table>