HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

Medicines & Healthcare products Regulatory Agency

Memorandum of Understanding between the Medicines and Healthcare products Regulatory Agency (MHRA) and Healthcare Safety Investigation Branch (HSIB)

1. Purpose

1.1 This Memorandum of Understanding sets out the framework to support the working relationship between the MHRA and the HSIB. It is intended to inform members of staff and the public about how the MHRA and the HSIB will work together.

1.2 The MHRA and the HSIB are independent bodies that recognise each other's statutory responsibilities, but will seek to collaborate and co-operate where relevant and lawful to do so in furthering our shared aim of improving patient safety and system-wide learning and improvement.

1.3 Each organisation will take steps to ensure that relevant staff are aware of what is in this Memorandum. They will keep staff updated both about any changes to it and the responsibilities it places on each organisation and the work that they do.

1.4 This Memorandum is not intended to be legally binding, and no legal rights or obligations will arise between the MHRA and the HSIB from this Memorandum.

2. Legislative Framework and Core Functions

The Medicines and Healthcare products Regulatory Agency (MHRA)

2.1 The MHRA is an Executive Agency of the Department of Health and was established on 1 April 2003. The Agency has three core functions:

- The Medicines and Healthcare products Regulatory Agency (MHRA) regulatory centre. The MHRA is the UK's regulator of medicines, medical devices and blood components for transfusion. The regulatory centre has a statutory function to supervise the system to ensure their safety, quality and efficacy/performance, as set out in the Human Medicines Regulations 2012 for medicines and the EU Regulation on Medical Devices 2017/745 and the EU Regulation on In Vitro Diagnostic Medical Devices 2017/746 for devices. It also supports innovation and new products being developed safely for the benefit of public health, monitors the safety of medicines devices and blood and works with the Department of Health and Social Care and the NHS to ensure secure supply in globalised industries

- The Clinical Practice Research Datalink (CPRD) is a non-statutory data research service that aims to improve public health by using anonymised NHS clinical data

- The National Institute for Biological Standards and Control (NIBSC) is a non-statutory a global leader in the standardisation and control of biological medicines

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

2.3 The MHRA's objectives are to:

- Safeguard public health through ensuring that the products it regulates meet required standards of safety, quality and efficacy;

- Carry out a 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 facilitates innovation.
- Influence the shape of the future regulatory framework through the use of effective European and international relationships; and
- Run an organisation with a skilled and equipped workforce that is fit for the future.

2.4 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 and directly auditing medical device manufacturers where necessary;
- Encouraging the reporting of suspected problems with both medicines and devices and investigating reports, including action where necessary, and the communication of regulatory action when taken; and
- Investigating and prosecuting, where necessary, cases of non-compliance.

3. The Healthcare Safety Investigation Branch (HSIB)

3.1 The HSIB is a safety investigation body established under the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 and the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018. The HSIB was set up to discharge the Secretary of State's duties in relation to the promotion of a comprehensive health service and securing continuous improvement in the quality of services.

3.2 The HSIB's purpose is to:

- Conduct thorough, independent, impartial and timely investigations into clinical incidents.
- Engage patients and relatives, NHS staff, and national organisations throughout the investigation process.
- Produce clearly written, thorough and concise reports with well-founded analysis and conclusions that explain the circumstances and causes of clinical incidents without attributing blame.
- Make safety recommendations to improve patient safety.
- Improve patient safety by sharing the lessons learned from investigations as widely as possible.
- Raise the standard of local investigations of healthcare safety incidents by establishing common standards and skills development.

4. Principles of Co-operation

4.1 This Memorandum is a statement of principle which supports our focus on promoting patient and public safety and wellbeing. More detailed operational protocols shall be developed in support of this principle.

4.2 The MHRA and the HSIB intend that their working relationship be characterised by the following:

- The need to make decisions which promote people's safety and high-quality health and social care.
- Respect for each organisation's independent status.
- The need to maintain public and professional confidence in the two organisations and the regulatory process.
- Openness and transparency between the two organisations as to how they share information in relation to safe space and taking into consideration necessity and/or appropriateness of the sharing.
- Addressing gaps in the regulatory framework via safety recommendations.

5. Areas for co-operation

5.1 Where the MHRA and the HSIB encounter concerns which they believe may fall within the remit of the other, they will consult and co-operate together to fulfil their respective functions as fully, effectively and efficiently as possible.

The MHRA and the HSIB will consult with each other on making practical arrangements for the co-ordination of investigations into the same or related incidents. Unless both parties agree, neither party shall take part in the other party's investigation.

6. Information Sharing

6.1 It is anticipated that the number of cases that overlap between the MHRA and the HSIB's respective investigations will be small. The parties shall formalise a separate information sharing agreement for the lawful exchange of personal data between the MHRA and the HSIB. This information sharing agreement will be reviewed annually and will specify how both organisations will meet their obligations under the Data Protection Act 2018 and the General Data Protection Regulation (EU) 2016/679.

7. Liaison Meetings

7.1 The MHRA and the HSIB may wish to meet to share relevant and appropriate information and intelligence and any strategic developments which may impact on each other's work.

8. Monitoring and Reviewing of this Memorandum

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

8.2 To support effective and timely contact, details of key contacts within the MHRA and the HSIB are contained in Annex A. They shall liaise as required to ensure this Memorandum is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.

8.3 Either party may suggest amendments to the Memorandum but the approval of both will be required to make a change.

8.4 The MHRA and the HSIB will ensure that the other has been provided with appropriate named contacts to liaise as required to carry out day to day business.

9. Resolution of Disagreement

9.1 Where either party identifies problems in operating this Memorandum, it will seek to resolve them quickly and informally. If this is not possible then the Chief Executive of the MHRA and the Chief Investigator of the HSIB will take responsibility for achieving a mutually acceptable resolution. Their decision will be final.

Dated 16/04/20

Signed by [redacted]

Chief Investigator of the Healthcare Safety Investigation Branch

Dated ...29/04/2020 ....

Signed by

[redacted]

Chief Executive Medicines and Healthcare Products Regulatory Agency

Annex A: Contact details for all parties

Named contacts between CQC and MHRA are as follows:

Relationship Leads: (First points of contact for any specific matters relating to this Memorandum)		
	MHRA	**HSIB**
Name:	**Victoria Crawford (policy)**	**Matthew Wain**
Position:	Policy and Strategic Partnerships	Principal National Investigator
Email:	[redacted]	[redacted]
Tel:	[redacted]	[redacted]

Chief Executive	
Dr June Raine CBE Interim Chief Executive [redacted]	**Keith Conradi** Chief Investigator [redacted]

Other Useful Contacts: (e.g. Media Team, Legal Team etc.)		
	MHRA	**HSIB**
Name:	Dr Duncan McPherson	Dr Stephen Drage
Position:	Clinical Director Devices	Director of Investigations
Email:	[redacted]	[redacted]
Tel:	[redacted]	[redacted]
Name:	Kyle Christie	Kirsty Benn-Harris
Position:	Digital and Strategic Content Manager	Associate Director of Data Compliance and Information Governance
Email:	[redacted]	[redacted]