Medicines & Healthcare products Regulatory Agency

Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Gwirio bod pobl yng Nghymru yn derbyn gofal da

Checking people in Wales are receiving good care

Memorandum of Understanding (MoU) between Healthcare Inspectorate Wales (HIW) and the Medicines and Healthcare products Regulatory Agency (the Agency)

Contents

Revision history and approval

Version	1.0
Date created	November 2017
Authors	HIW: Huw Jones The Agency: Paul McCormack
Date agreed	30 January 2018
Formally agreed by	HIW: Kate Chamberlain The Agency: Ian Hudson
Review date	January 2020

Introduction

1. The purpose of this Memorandum of Understanding (MoU) is to set out a framework to support the working relationship between Healthcare Inspectorate Wales (HIW) and the Medicines and Healthcare products Regulatory Agency ('the Agency').

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

3. This MoU relates only to the regulation of healthcare in Wales. It does not override the statutory responsibilities and functions of HIW and the Agency 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.

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

Roles and responsibilities

Healthcare Inspectorate Wales

5. HIW is the independent inspectorate and regulator of healthcare in Wales. HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational autonomy. HIW's main functions and responsibilities are drawn from the following legislation:

    - Health and Social Care (Community Health and Standards) Act 2003;
    - Care Standards Act 2000 (and associated regulations);
    - Mental Health Act 1983 and 2007, Mental Health (Wales) Measure 2010;
    - Independent Health Care (Wales) Regulations 2011;
    - Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008; and
    - Ionising Radiation (Medical Exposure) Regulations 2000 and Amendment Regulations 2006.

6. HIW's priorities are to:

    - provide assurance: provide an independent view on the quality of care;
    - promote improvement: encourage improvement through reporting and sharing of good practice; and

- influence policy and standards: use what we find to influence policy, standards and practice.

7. HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public, and others that services are safe and of good quality. Health services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services to ensure that rapid improvement and learning takes place.

8. HIW is also responsible for the registration and regulation of independent healthcare providers under the Care Standards Act 2000. The regulation of such establishments is governed by the Independent Health Care (Wales) Regulations 2011.

The Medicines and Healthcare products Regulatory Agency

9. The Agency 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; and
- The 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.

10. The MHRA regulatory centre 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.

11. 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 of co-operation

12. HIW and the Agency acknowledge their respective statutory and non-statutory responsibilities and functions, and will take account of these when working together.

13. In implementing this agreement, HIW and the Agency intend that their working relationship will be characterised by the following principles:

- the need to make decisions that promote high quality healthcare and which protect and promote patient health, safety and welfare;
- full openness and transparency between the two organisations as to when cooperation is, and is not, considered necessary or appropriate;
- respect of each other's independent status;
- the need to use resources and intelligence effectively and efficiently through appropriate coordination and information sharing;
- the need to maintain public confidence in the two organisations; and
- a commitment to address any identified overlaps or gaps in the regulatory framework and responsibilities.

14. HIW and the Agency are also committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of better regulation).

Joint Priorities and Areas of Work

Exchange of Information

15. Co-operation between HIW and the Agency will often require the exchange of information. Exchange of information will be expected, but not limited, to cases where:

    - either HIW or the Agency identifies concerns 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 and those concerns are considered to be relevant to the other organisation's regulatory functions; and
    - a resolution to a concern would benefit from a coordinated multi-agency response.

16. In such cases, all exchanges of information will be lawful and proportionate and shared in confidence with the named contact in the other organisation at the earliest possible opportunity.

17. All arrangements for co-operation and exchange of information set out in this MoU and any joint working protocol that may be developed will take account of and comply with the Data Protection Act 1998, Freedom of Information Act 2000**,** Health and Social Care (Community Health and Standards) Act 2003, section 76 of the Health and Social Care Act 2008, Care Standards Act 2000, the Clinical Trials Directive (Directive 2001/20/EC), and all relevant HIW and Agency legislation relating to these matters, and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

18. Both HIW and the Agency 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.

Media and Publications

19. HIW and the Agency will seek to give each other adequate warning of, and sufficient information about, any planned announcements to the public on issues relevant to both organisations, including the sharing of draft proposals and publications.

20. HIW and the Agency commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations.

21. HIW and the Agency respect confidentiality of any documents shared in advance of publication and will not act in any way that would cause the content of those documents to be made public ahead of the planned publication date.

Governance

22. The effectiveness of the working relationship between HIW and the Agency will be supported by regular contact, either formally or informally.

23. At a minimum, there will be an annual meeting between Chief Executives to discuss strategic concerns relevant to both organisations. Meetings to discuss intelligence, policy and operational issues of interest to both organisations should take place between relevant colleagues at both organisations when appropriate, and at least twice a year. Contact details of relevant operational level contacts in each organisation are shown at Annex A.

24. Any disagreement between HIW and the Agency will normally be resolved at working level. If this is not possible, it must be brought to the attention of the MoU managers identified at Annex A, who may then escalate it as appropriate within the two organisations to reach a mutually satisfactory resolution. Both organisations should aim to resolve disagreements in a reasonable time.

Duration and review of this MoU

25. Both organisations have identified a person responsible for the management of this MoU in Annex 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.

26. This MoU is not time-limited and will continue to have effect unless the principles described need to be altered or cease to be relevant. This MoU will be reviewed annually by the MoU managers identified at Annex A, but may also be reviewed more urgently at any time at the request of either organisation.

Signed

Dr Kate Chamberlain

Chief Executive

Healthcare Inspectorate Wales

Date: 30 January 2018

Dr Ian Hudson

Chief Executive

Medicines and Healthcare products Regulatory Agency

Date: 30 January 2018

Annex A – Contact Details

Healthcare Inspectorate Wales	**Medicines and Healthcare products Regulatory Agency**
Welsh Government Rhydycar Business Park Merthyr Tydfil CF48 1UZ	151 Buckingham Palace Road London SW1W 9SZ
Tel: 0300 062 8163	Tel: 020 3080 6000

There will be named contacts between HIW and the Agency as follows:

Chief Executives	
Dr Kate Chamberlain *Chief Executive* kate.chamberlain@gov.wales	**Dr Ian Hudson** *Chief Executive* ian.hudson@mhra.gov.uk
Senior Responsible Officials	
Alun Jones *Deputy Chief Executive* alun.jones39@gov.wales Tel: 0300 062 8220	**Jonathan Mogford** *Director of Policy* jonathan.mogford@mhra.gov.uk Tel: 020 3080 6600
MoU managers	
Huw Jones *Corporate Intelligence Analyst* huw.jones@gov.wales Tel: 0300 025 5996	**Paul McCormack** *Head of Strategic Partnerships* paul.mccormack@mhra.gov.uk Tel: 020 3080 6965
Communications and Media	
Natalie Jones *Communications and Engagement Manager* HIWcomms@wales.gsi.gov.uk Tel: 0300 062 8382	**Malcom Evans** *Head of Patient, Public and Stakeholder Engagement* malcolm.evans@mhra.gov.uk Tel: 020 3080 7016

	Jennifer Kyne *Head of News, Digital and Content* jennifer.kyne@mhra.gov.uk Tel: 020 3080 6638

Operational level contacts for particular topics at HIW and the Agency are as follows:

Patient Safety issues	
Darren Hatton *Corporate Intelligence Manager* darren.hatton@gov.wales Tel: 0300 062 8402	**Ben Scott** *Patient Safety & Vigilance Strategy Delivery Manager, Communications Division* ben.scott@mhra.gov.uk Tel: 020 3080 6725

Medicines Safety issues	
Zoe Weaver *Head of NHS Inspection* zoe.weaver@gov.wales Tel: 0300 062 8539	**Sarah Morgan** *Group Manager, Vigilance & Risk Management of Medicines Division* sarah.morgan@mhra.gov.uk Tel: 020 3080 6763

Medical Devices Safety issues	
Zoe Weaver *Head of NHS Inspection* zoe.weaver@gov.wales Tel: 0300 062 8539	**Janine Jolly** *Devices Safety Unit Manager, Devices Division* janine.jolly@mhra.gov.uk / aic@mhra.gov.uk Tel: 020 3080 6690

Enforcement issues	
Matt Thomas *Enforcement and Escalation Manager* matthew.thomas@gov.wales Tel: 0300 062 8255	**Lynda Scammell** *Relationship Manager / Senior Policy Manager, Inspection, Enforcement & Standards Division* lynda.scammell@mhra.gov.uk Tel: 020 3080 6665

Clinical trials	
Andrew Pryse *Head of Independent Healthcare and Statutory Functions* andrew.pryse@gov.wales Tel: 0300 062 8220	**Martin O'Kane** *Clinical Trials Unit Manager, Licensing Division* **Martin.o'kane@mhra.gov.uk** Tel. 0203 080 6659