Medicines & Healthcare products
Regulatory Agency

Burden Reduction Plan for National Information Collections

May 2016

CPRD NIBSC MHRA

Contents

1. Introduction

The primary purpose of the health and social care system is to improve outcomes for people who use its services. The new health and care system has been designed to give greater influence to citizens and service users.

Everyone involved in health, public health and social care needs access to accurate and timely information to carry out their duties. We also have a public duty to collaborate in the interests of good care and outcomes, and in the interests of efficiency and productivity. We must obtain that information efficiently, so that it is not at the expense of direct care to people who need the services. As far as possible, this will be done by ensuring the information is captured as part of the care-giving process, is recorded in standard ways, and is capable of being extracted automatically to remove the need for separate collection or reporting processes.

The Medicines and Healthcare products Regulatory Agency (the Agency) collects information from healthcare professionals and the public for the purpose of monitoring the safety of medicines and devices used in clinical practice and to enable the Agency to take appropriate action to protect public health. . This is vital work which is undertaken to optimise the health of patients using these products and to respond swiftly to patient safety incidents.

2. Purpose of the Burden Reduction Plan for National Information Collections

Following the recommendations from the NHS Confederation in their report on reducing burdens in November 2013, a set of core principles (a concordat[1]) governing the collection of data from NHS bodies, to secure a more collaborative and systematic approach to data collections across the health and social care system, was put together and signed by the Department of Health (DH) and each ALB.

To further support and strengthen the burden reduction activity in accordance with the concordat, George Freeman MP wrote to all ALB Chief Executive Officers requesting commitment to the development of a 2016/17 Burden Reduction Plan for reducing burden relating to their ALB's data collections. MHRA refers henceforth to this document as its Burden Reduction Plan for National Information Collections, which is one part of the Agency's wider burden reduction work.

In summary, the concordat for reducing burden asks DH and its ALBs to:

- collect data which is proportionate and with a clear business purpose
- not duplicate other data collections
- work through the HSCIC as the national base for all data
- review the need to collect the data regularly

This plan shares MHRA plans to continue to minimise burden in its information collection activity where appropriate to do so and to put in place a timeline for monitoring success.

[1] https://www.gov.uk/government/publications/reducing-burden-of-national-requests-for-information-concordat

3. About the Medicines and Healthcare products Regulatory Agency

The regulatory centre of the Medicines and Healthcare products Regulatory Agency (the MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. It is an executive agency of the Department of Health.

Recognised globally as an authority in its field, MHRA plays a leading role in protecting and improving public health and supports innovation through scientific research and development. MHRA is responsible for:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality, efficacy and performance
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- supporting innovation and research and development that's beneficial to public health
- influencing UK, EU and international regulatory frameworks so that they're risk-proportionate and effective at protecting public health

The Clinical Practice Research Datalink has been part of the Agency since 2013. Its purpose is to provide access to anonymised primary care data for the purpose of medical research.

4. National Information Collections

The estimated total collection burden of MHRA in 2013 was £494,397, which was less than 1% of the national collection burden. Table 1, overleaf, provides a breakdown of the MHRA's estimated data collection burden. The figures represent the burden of collections which have been recorded through the Health and Social Care Information Centre's Burden Advice and Assessment Process (formerly the Review of Central Returns process).

It is acknowledged that these published figures now need to be updated in collaboration with the Health and Social Care Information Centre. The necessity for the collections remains extant as they are critical to the MHRA's role in ensuring public safety in relation to medicines, vaccines, devices and blood products. Adverse incident reporting enables potential safety issues to be identified and investigated quickly, and an appropriate response put in place quickly to reduce risk to patients and the public.

The largest single proportion of MHRA's collection burden (just under half) is represented by the Central Alerting System (CAS)[2]. CAS informs healthcare professionals about important safety issues which may require their action in the interests of public health. It requires the recipients of MHRA safety alerts to acknowledge receipt, followed by implementation and completion of action plans to assure the safety of patients and the public. The remaining burden results from reporting on adverse incidents involving medicines, vaccines, medical devices and blood products. These collections are undertaken for the essential purpose of assuring public safety.

The Agency has a legal obligation under the Pharmacovigilance Directive 2010/84/EU[3] to record all adverse reaction information provided by healthcare professionals and patients and to provide a means by which these reports may be submitted. The Directive requires specifically that Member States 'take all appropriate measures to encourage patients, doctors, pharmacists and other health-care professionals to report suspected adverse reactions'. In addition the Medical Devices Directive (2007/47/EC[4]) and the In Vitro Diagnostic Medical Devices Directive (98/79/EC[5]) include requirements for medical device manufacturers to report certain types of incidents to competent authorities (i.e. MHRA in the UK).

The UK reporting system for adverse medicine and medical device events is non-mandatory for healthcare professionals and patients, in order to encourage early no-blame reporting of adverse reactions and events so that they may be dealt with promptly and effectively.

Reporting on serious adverse events relating to blood products is mandated through the EU Blood Safety and Quality Regulations under Directive 2002/98/EC[6].

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[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Ac11565

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0074:0099:EN:PDF

[4] http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32007L0047

[5] http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices/index_en.htm

[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:033:0030:0040:EN:PDF

MHRA launched the Yellow Card app in 2015 to make it easier and quicker for healthcare professionals and the public to submit information on adverse events involving medicines and vaccines and has done significant work to integrate reporting of adverse reaction into existing healthcare systems to reduce the time taken to report.

The Clinical Practice Research Datalink (CPRD), which provides anonymised primary care data to researchers, directly collects data already recorded by medical practitioners. The data is collected by automated systems and therefore creates no additional burden. Primary care data collected can be linked to other existing data sets through linkage undertaken by the HSCIC for CPRD. This uses existing linkage methodology in use at the HSCIC thereby avoiding additional burden. From time to time practitioners are invited to take part in clinical trials and data verification studies. This is voluntary and they are paid for this work, which supports research that benefits public health and contributes towards the development of new medicines.

Table 1: MHRA Collections on the HSCIC Burden Advice and Assessment Service Online Catalogue

What does the MHRA collect?	How often and from whom?	Why is it collected?
Central Alerting System (CAS): Trusts' responses to safety alerts. **Estimated Annual Burden 2013: £238,085**	Continuous	This requirement is part of the former Chief Medical Officer's initiative to provide all NHS Trusts and Local Area Teams of NHS England with a tool to improve and monitor response to safety alerts as set out in 'Standard for Better Health'. Whilst no specific standard is given in the Care Quality Commission Regulations, safety and quality are the underpinning values of the regulations. Failure to respond to alerts will be reflected in the Care Quality Commission's Quality Risk Profile for the Trust and the Trust would also be rated as 'Poor' by NHS Choices in the patient safety section of its profile.
Adverse incident reporting for medical devices. **Estimated Annual Burden 2013: £42,864**	Continuous	This is a pan-EU requirement. Collection of this information enables MHRA to be alerted to potential issues relating to medical devices post-marketing, to conduct analysis of data provided and to respond where necessary in order to optimise patient safety. There are around 17,000 reports every year.
Serious Adverse Blood Reactions & Events (SABRE). **Estimated Annual Burden 2013: £65,683**	Continuous	This requirement is mandated by the EU Blood Safety & Quality Regulations. It enables MHRA to respond to adverse blood reactions and events and provide the UK Competent Authority return to the EU Commission. There are around 2,400 reports every year.
Yellow Card Reporting (adverse incidents involving medicines and vaccines). **Estimated Annual Burden 2013: £147,764**	Continuous	Collection and analysis of this information enables MHRA to respond to adverse drug reactions (prescription medicines, vaccines, over-the-counter medicines and herbal remedies). An NHS information standard has been created to enable Yellow Cards to be sent from clinical IT systems to help improve the numbers of reports received by the MHRA, and to reduce the burden on reporters by using information already within their existing systems. MHRA receives around 20,000 reports every year.

Further information on MHRA data collection is available via the HSCIC's Central Register of Assessed Collections[7]

[7] https://rocrsubmissions.ic.nhs.uk/Pages/search.aspx?k=R*

5. Minimising Burden

The Agency is fully committed to a wide programme of continuous burden reduction, including but not limited to the requirement to contribute monetised burden savings for industry as part of the government's Business Impact Target[8]. MHRA demonstrated its strong commitment to burden reduction during the Red Tape Challenge[9] in the last Parliament and has also provided an Innovation Plan to the Department of Health in line with the requirements of the UK's Productivity Plan[10], published in July 2015. MHRA is fully committed to this work, with supporting innovation as a key theme throughout its corporate strategy and business planning.

The principles of the Concordat on Reducing Burden of National Requests for Information are designed to reduce any unnecessary burden on those providing information to public health bodies. MHRA keeps the ease of use of its collection systems under regular review; however wishes to ensure that healthcare professionals and the public continue to be encouraged to report adverse events to enable it to undertake the crucial work of ensuring patient safety through early management. Some of the Concordat's requirements are not applicable to the Agency in this regard. Table 2, below, details MHRA plans against the individual Concordat commitments where applicable.

Table 2: MHRA Plans for Reducing Burden of National Requests for Information

Serial	Concordat Requirement	Description of activity	Timescale/Progress
1	Only collect information from service providers where there is a clear business purpose which justifies the administrative burden required to provide the information	There is a strong public and professional interest in current MHRA data collections continuing as their purpose is the assurance of public safety. MHRA will continue to evaluate ways to ensure reporting mechanisms are as straightforward as possible and minimise any burden for the reporter.	Review by September 2016

[8] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/503155/bis-15-694-enterprise-bill-bit.pdf

[9] www.redtapechallenge.cabinetoffice.gov.uk

[10] www.gov.uk/government/uploads/system/uploads/attachment_data/file/443898/Productivity_Plan_web.pdf

Serial	Concordat Requirement	Description of activity	Timescale/Progress
2	Work with the Health and Social Care Information Centre (HSCIC) as the national base for all information which is collected or extracted from local systems;	Not applicable. MHRA's national data collections are independent of HSCIC.	N/A
3	Establish clear criteria which can be used to measure the administrative burden arising from each national request for information	Data on collection burden currently held by HSCIC to be reviewed and updated in line with HSCIC standards.	Review by September 2016
4	Through the HSCIC, publish details of all the national collections and extractions, and the criteria that are used to justify each decision;	Burden estimates relating to four of MHRA's own national collections are published through HSCIC but require reviewing and updating.	Review by September 2016
5	Where appropriate, ensure that all aggregated and non-personal information that collected is made available for others to use, in the interests of transparency and avoiding duplication.	The Agency operates on a principle of transparency as far as is appropriate but will also be reviewing its transparency policy relating to data collections and other information to ensure that aggregated, non-personal information is made available to further audiences where possible.	Review by September 2016
6	Agree with the HSCIC an annual MOU which sets out each organisation's commitment to an agreed reduction in data collections that are undertaken outside the national process managed by the HSCIC;	Not applicable. MHRA data collections are undertaken for safety purposes and in accordance with legislation. The data collection burden is assessed and published by HSCIC.	N/A

Serial	Concordat Requirement	Description of activity	Timescale/Progress
7	Making better use of technology to introduce more efficient ways of acquiring the information, especially by moving away from manual collections to automated extractions of data directly from local systems, and using existing data held nationally;	The data collected by MHRA is specific to adverse incident and alerting requirements; therefore it requires either manual input specific to an incident, or confirmation of specific action plans being put in place by companies following an incident. The systems being used by MHRA are under review as part of the wider Agency digital strategy; however a key milestone was the launch of the Yellow Card app in 2015 to make adverse incident reporting for medicines and vaccines quicker and simpler for healthcare professionals and the public. Significant progress has also been made on the integration of incident reporting into clinical systems, reducing the time taken to report incidents to the MHRA.	Ongoing.
8	Ensuring that the collections and extractions are aligned with robust professional practice, such as NICE or other professional guidelines, and information standards;	Data is currently collected and handled in line with professional practice and the Data Protection Act. The Agency keeps its practice under regular review to ensure it continues to meet guidelines and best practice.	Ongoing
9	Reducing and retiring those national requests for information that are no longer needed or justifiable	Current MHRA data collections are necessary for the purpose of assuring public safety and are undertaken in accordance with legislation.	Review annually.
10	Keep these arrangements under regular review and contribute to the HSCIC's annual report detailing their progress in reducing burden, with clear reference to the targets agreed in the MOU.	The Agency will continue to contribute to HSCIC annual reporting, as required.	Ongoing

Serial	Concordat Requirement	Description of activity	Timescale/Progress
11	Work closely with the HSCIC on the three year review of existing data collections to make sure that collections are still necessary, are not being collected elsewhere, and are collected in the most efficient and least burdensome way possible	MHRA will collaborate with HSCIC as required in any review.	As required
12	Work closely with the HSCIC when designing new data collections to ensure that they are not duplicating any other existing data collection and that they are designed in a way to minimise burden on the service	No new data collections planned currently; however any collections undertaken in future will be designed with the input and advice of HSCIC and other stakeholders.	As required

6. Next Steps

The Agency will work with HSCIC within the first half of 16/17 to review and update its estimated data collection burdens and will continue to review annually.

Signed: Ian Hudson

Name and position: Chief Executive

Organisation: Medicines and Healthcare products Regulatory Agency

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