Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DCB1582 Amd 16/2017 Electronic Yellow Card Reporting

Specification - Change Paper

Amendment History:

Version	Date	Amendment History
0.1	15/08/2017	Draft version 1
1.0	13/09/2017	Updated in response to SME feedback

Data Coordination Board

This information standard (DCB1582) has been approved for publication by the Department of Health under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Coordination Board (DCB), a sub-group of the Digital Delivery Board.

This information standard comprises the following documents:

- Requirements Specification
- Implementation Guidance
- Change Specification.

An Information Standards Notice (DCB1582 Amd 16/2017) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 26 October 2017.

Contents

1 Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) collects reports of suspected adverse drug reactions (ADRs) via the Yellow Card Scheme. These provide a source of information on potential drug safety issues allowing the agency to take regulatory action to protect public health. Healthcare professionals report ADRs either by completing a paper form or a form on an external website/App. DCB1582 Electronic Yellow Card Reporting (formally ISB Electronic Yellow Card Reporting) defines a method for submitting the information electronically; this allows IT systems to reduce the burden on the clinician by populating the majority of the Yellow Card submission from the patient's electronic record.

This change paper outlines amendments which have been made to the updated version of the specification. Changes to the Requirements, Conformance Criteria, Message Fields and Validation document and the example ICSR xml messages have been made to enhance system supplier understanding. These changes were deemed necessary as a result of misinterpretation during previous implementations. The changes will hopefully also lower the risk of transcribing and translational errors from the healthcare professional user. In addition, minor wording amendments have been made to keep the specification current. The xml Document Type Definition (DTD) previously approved has not required any updates.

Organisations that have already implemented the Standard MUST consider this 'change paper' and take any necessary steps to ensure that they remain compliant.

Organisations that have not previously implemented the Standard MUST consider this 'change paper' alongside the reissued Specification, to ensure that they implement the Standard correctly and completely.

2 Changes to the Summary, Controlled Documents and Related Standards

2.1 Summary

There has been a small amendment made to the description of the Standard to reflect the additional app based reporting method.

There has been an amendment in the summary to highlight what is in scope of the Standard and what falls outside of the scope.

The section now includes:

'In Scope'

The standard is for providers of NHS care or treatment and medical/clinical teams in other health organisations. It is intended to be used in, but is not limited to:

- GP Surgeries / Primary care.
- Pharmacies.
- Acute hospitals.
- Community, day hospitals, day services, outpatient clinics.
- The patient's home or any other remote setting (depending on the specific NHS organisation's infrastructure and technological capability).

Exclusions

The Standard is currently out of scope and not intended for use for the following groups:

- Patients
- Parents/Carers

2.2 Controlled Documents

The following controlled documents have been amended to include the updated supporting documents. No changes were made to the electronic Yellow Card message document type definition. References to these documents have been updated throughout the Specification.

Document Reference	Name
DCB 1582 electronic Yellow Card message fields and validations v3.0	Electronic Yellow Card message field list, validations and lists of values.
E2BX_ICSR.DTD	Electronic Yellow Card message document type definition
ExampleICSR v3 0.xml	Example of an electronic Yellow Card message which meets validation requirements

ExampleICSRfail v3 0.xml	Example of an electronic Yellow Card message which fails validation requirements

2.3 Related Standards

The Related Standards have been revised to include the most recent versions. DCB 1553 READ Version 2 and DCB 1552 READ Clinical Terms Version 3 have been removed as they are now deprecated. The new links are:

Reference	Title
ICH E2B(R2)	Electronic Transmission of Individual Case Safety Reports Message Specification (ICH ICSR DTD Version 2.3)
SCCI0052	Dictionary of medicines and devices (dm+d)
SCCI0034	SNOMED CT

3 Changes to the Definition of the Standard, including Requirements and Conformance Criteria sections

3.1 Changes to Information Specification Section.

This section has been updated to provide the new link to the updated message fields and validations spreadsheet. It now reads:

Please see the spreadsheet DCB1582 electronic Yellow Card message fields and validations v3.0 for a definition of the message field values, data requirements and validations.

Updates to this document are described below:

Document Reference	Current Text	Proposed Text
Message Fields and Validations document.xls 1st Tab, list of validations	Data element missing	Data element added: To add to row 58 **B.1.1.1 patientinitial** Map from system Field Source and Size Mapped 10AN
Message Fields and Validations document.xls 1st Tab, list of validations	Data element missing	Data element added: To add to row 87-88 **B.4.k.5.1 drugstructuredosagenumb** Field source and size Mapped 8AN **B.4.k.5.2 drugstructuredosageunit** Field source and Size Mapped 3AN drugstructuredosageunit field should be completed with unit code (see drugstructuredosageunit tab)
Message Fields and Validations document.xls 5th Tab	Data element missing	Drugstructuredosageunit tab added with details of the 3AN length codes: 001=kg kilogram(s) 002=G gram(s) 003=Mg milligram(s) 004=µg microgram(s)

		005=ng nanogram(s) 006=pg picogram(s) 007=mg/kg milligram(s)/kilogram 008=µg/kg microgram(s)/kilogram 009=mg/m 2 milligram(s)/sq. meter 010=µg/ m 2 microgram(s)/ sq. Meter 011=l litre(s) 012=ml millilitre(s) 013=µl microlitre(s) 014=Bq becquerel(s) 015=GBq gigabecquerel(s) 016=MBq megabecquerel(s) 017=Kbq kilobecquerel(s) 018=Ci curie(s) 019=MCi millicurie(s) 020=µCi microcurie(s) 021=NCi nanocurie(s) 022=Mol mole(s) 023=Mmol millimole(s) 024=µmol micromole(s) 025=Iu international unit(s) 026=Kiu iu(1000s) 027=Miu iu(1,000,000s) 028=iu/kg iu/kilogram 029=Meq milliequivalent(s) 030=% percent 031=Gtt drop(s) 032=DF dosage form
ExampleICSR.xml	Data elements missing	Data elements added: **Patientinitial** **Drugstructuredosagenumb** **Drugstructuredosageunit**
ExampleICSRfail.xml	Data elements missing	Data elements added: **Patientinitial** **Drugstructuredosagenumb** **Drugstructuredosageunit**

In addition to the changes above, links to the NHS data dictionary field that are no longer relevant have been removed.

3.2 Changes to Requirements and Conformance Criteria

The table below details the changes made to the Requirements and Conformance Criteria.

Document Reference	Current Text	New text
Standard Specification 2.0 document Page 20 section 6.2 Requirements #9	If a user selects an option to complete a Yellow Card at a later stage, a system for reminding the user **MUST** be in place.	If a user selects an option to complete a Yellow Card at a later stage an automated system for reminding the user **MUST** be in place.
Standard Specification 2.0 document Page 20 section 6.2 Requirements #11	A user **MUST** be able to retrieve a Yellow Card previously completed by entering the safetyreportid so that additional information on the patient or adverse drug reaction may be provided to the MHRA on request. (Responses to follow up information requests are not via transmission of an electronic Yellow Card message).	A user **MUST** be able to retrieve a Yellow Card previously completed by entering the safetyreportid so that additional information on the patient or adverse drug reaction may be provided to the MHRA on request. (Responses to follow up information requests are not via transmission of an electronic Yellow Card message). The search function should span across the organisation (e.g. surgery) in order to identify the Yellow Card. The system should list all previously submitted Yellow Cards.
Standard Specification 2.0 document Page 21 section 6.2 Requirements #18	Medical terms **MUST** be populated using SNOMED CT term concept IDs or MedDRA Lower Level Terms IDs (LLTs). Read V2, Read V3 or CTV3 terms should first be mapped to SNOMED CT concept IDs using a NHS TRUD cross-map. Where no mapping exists, the MedDRA LLT code ‘10052538’ for ‘Adverse drug reaction NOS' **MUST** be populated.	Medical terms **MUST** be populated using SNOMED CT term concept IDs or MedDRA Lower Level Terms IDs (LLTs). Read V2, Read V3 or CTV3 terms **MUST** first be mapped to SNOMED CT concept IDs using a NHS TRUD cross-map. Where no mapping exists, the MedDRA LLT code ‘10052538’ for ‘Adverse drug reaction NOS' **MUST** be populated.
Standard Specification 2.0 document Page 21 section 6.2 Requirements #22	A Yellow Card **SHOULD** automatically populate patient weight and height when this is present in the patient record.	A Yellow Card **SHOULD** automatically populate patient weight and height when a current value is present in the patient record.
Standard Specification 2.0 document Page 21 section 6.2 Requirements #23	A Yellow Card **SHOULD** automatically populate patient medical history recorded in the past year (i.e. date recorded is within one year of the Yellow Card creation date).	A Yellow Card **MUST** automatically populate patient medical history in the XML field <patientepisodename> recorded in the past year (i.e. date recorded is within one

		year of the Yellow Card creation date). The medical history terms **MUST** be populated using SNOMED CT Concept IDs or MedDRA LLTs. (Refer to requirement 18 for more details).
Standard Specification 2.0 document Page 21 section 6.2 Requirements #26	All current repeat medications and any discontinued repeat or acute medication prescribed to a patient in the three months prior to the date of the Yellow Card creation date **MUST** be populated using dm+d entries, using the most detailed term level available (AMP>VMP>VTM>Active substance).	All current repeat medications and any discontinued repeat or acute medication prescribed to a patient in the three months prior to the date of the Yellow Card creation date **MUST** be populated using dm+d entries, using the most detailed term level available (AMP>VMP>VTM>Active substance). For any repeat medications this should be limited to one entry with the initiation date
Standard Specification 2.0 document Page 21 section 6.2 Requirements #27	A user **MUST** also be able to enter medicines entered using free text where dm+d cannot provide a suitable term.	A user **MUST** also be able to enter a suspect or concomitant medicine using free text where dm+d cannot provide a suitable term. For example: an unlicensed medicine purchased on the internet
Standard Specification 2.0 document Page 21 section 6.2 Requirements #28	The user **MUST** select one or more medicines to indicate a suspicion of having caused (i.e. may have caused) the adverse drug reaction.	The user **MUST** select one or more medicines to indicate a suspicion of having caused (i.e. may have caused) the adverse drug reaction. The number of suspect medicines **MUST NOT** be limited to any number
Standard Specification 2.0 document Page 21 section 6.2 Requirements #29	A Yellow Card **MUST** include at one or more suspect reactions (coded using SNOMED CT concept IDs or MedDRA LLTs) and a reaction outcome for every reaction as selected by the user. (The list of outcome values is provided in DCB1582 electronic Yellow Card message fields and validations v3 0. Reaction outcome **MUST** be populated as 'unknown' if not known or is not available to the reporter).	A Yellow Card **MUST** include at least one or more suspect reactions (coded using SNOMED CT concept IDs or MedDRA LLTs) and a reaction outcome for every reaction as selected by the user. (The list of outcome values is provided in DCB 1582 electronic Yellow Card message fields and validations. Reaction outcome **MUST** be populated as 'unknown' if not known or is not available to the reporter). The number of suspect reactions **MUST NOT** be limited to any number.
Standard Specification 2.0 document Page 22 section 6.2	For all medicine/drug entries populated, a Yellow Card **SHOULD** automatically include route of administration, dose,	For all suspect and concomitant medicine/drug entries populated a Yellow Card **SHOULD** automatically include

Requirements #30	start and stop dates, and indications when available from the patient record.	route of administration, dose, start and stop dates, and indications when available from the patient record
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #1	The IT system **MUST** be able to transmit the ExampleICSR v3 0.xml and ExampleICSRfail v3 0.xml messages to the MHRA webservice and receive the correct response.	The IT system is able to transmit the ExampleICSR v3 0.xml and ExampleICSRfail v3 0.xml messages to the MHRA webservice and receive the correct response
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #2	The IT system **MUST** be able to generate a XML message from data held in a test environment and data entered by a user, meeting minimum validation and all parsing requirements, transmit this to the MHRA webservice and receive the correct response.	The IT system can generate a XML message from data held in the test environment and data entered by a user, it meets the minimum validation and all parsing requirements. It is able to be transmitted to the MHRA webservice to receive the correct response.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #3	The IT system **MUST** be able to generate a XML message from data held in a test environment and data entered by a user, where the suspect drug was not available in dm+d, entered manually by a user, then transmit this to the MHRA webservice and receive the correct response.	The IT system can generate a XML message from data held in the test environment and data entered by a user. When the suspect drug is not available in dm+d, it is entered manually by a user. It is able to be transmitted to the MHRA webservice to receive the correct response.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #4	The IT system **MUST** be able to generate a fully populated message including repeated blocks for patient medical history, medications and reactions from data held in a test environment and data entered by a user, meeting validation and parsing requirements, transmit this to the MHRA webservice and receive the correct response.	The IT system can generate a fully populated XML message including repeated blocks for patient medical history, medications and reactions from data held in a test environment and data entered by a user. It meets validation and parsing requirements and can be transmitted to the MHRA webservice to receive the correct response.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #5	An IT system **MUST** be able to generate a fully populated XML message from data held in a test environment and data entered by a user, including all current repeat medications and any acute medication prescribed to a patient in the three months prior to the date of the Yellow Card creation date.	The IT system can generate a fully populated XML message from data held in the test environment and data entered by a user, including all current repeat medications and any acute medication prescribed to a patient in the three months prior to the date of the Yellow Card creation date.
Standard Specification 2.0 document Page 22 section 6.3	The Yellow Card XML message output corresponds to the information input from the	The Yellow Card XML message output corresponds to the information input from the

Conformance Criteria #6	system automatically and that added manually by the user.	system automatically and that added manually by the user.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #7	A user **MUST** be able to manually request a Yellow Card is created for a specific patient.	The IT System has function to enable all users to manually request a Yellow Card for a specific patient.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #8	The IT system **MUST** automatically prompt the user to complete an adverse drug reaction report when a medication previously on repeat-prescription is stopped and a user confirms a patient experienced an adverse drug reaction/drug intolerance/allergic drug reaction.	The IT system automatically prompts the user to complete an adverse drug reaction report when a medication previously on repeat-prescription is stopped and a user confirms a patient experienced an adverse drug reaction/drug intolerance/allergic drug reaction.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #9	If a user selects an option to complete a Yellow Card at a later stage, a system for reminding the user **MUST** be in place.	When a user selects an option to complete a Yellow Card at a later stage, an automatic system for reminding the user is in place.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #10	After the user requests that a Yellow Card be created, the system **MUST** provide a method for user entry of information which cannot be populated automatically from the patient record including reaction start and stop dates, additional medications and free-text information on reaction narrative, patient history and relevant tests.	After the user requests that a Yellow Card be created, the system provides a method for user entry of information which cannot be populated automatically from the patient record including reaction start and stop dates, medicines not available from dm+d, additional medications and free-text information on reaction narrative, patient history and relevant tests.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #11	An IT system user **MUST** be able to retrieve a Yellow Card previously completed by searching on the safetyreportid in order to provide additional information on the patient or adverse drug reaction when requested by the MHRA.	The IT system user can retrieve a Yellow Card previously completed by searching on the safetyreportid to provide additional information on the patient or adverse drug reaction when requested by the MHRA. The search function covers the whole organisation. The safetyreportid is unique and identifiable (e.g. electronically traceable).
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #12	An IT system **MUST** include an entry in the audit trail when a Yellow Card is generated and transmitted.	The IT system includes an entry in the audit trail when a Yellow Card is generated and transmitted.

Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #13	A Yellow Card message and a human readable version **MUST** be available to the user.	A Yellow Card XML message and a human readable version are available to the user. The human readable version reflects all information populated in the Yellow Card Message.
Standard Specification 2.0 document Page 22 section 6.3 Conformance Criteria #14	A system **MUST** create electronic Yellow Cards using the defined xml format using the ISO-8859-1, UTF-8 or UTF-16 character sets.	The system can create electronic Yellow Cards using the defined xml format using the ISO-8859-1, UTF-8 or UTF-16 character sets.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #15	Medical terms **MUST** be populated using SNOMED CT term concept IDs or MedDRA Lower Level Terms IDs (LLTs). Read V2, Read V3 or CTV3 terms should first be mapped to SNOMED CT concept IDs using a NHS TRUD cross-map. Where no mapping exists, the MedDRA LLT code '10052538' for 'Adverse drug reaction NOS' **MUST** be populated.	Medical terms are populated using SNOMED CT term concept IDs or MedDRA Lower Level Terms IDs (LLTs). If used, Read V2, Read V3 or CTV3 terms are first mapped to SNOMED CT concept IDs using a NHS TRUD cross-map. When no mapping exists, the MedDRA LLT code '10052538' for 'Adverse drug reaction NOS' is populated.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #16	The Yellow Card **MUST** have the patient age at time of reaction and sex automatically populated from the patient record when this is present in the patient record	The Yellow Card has the patient age at the time of reaction and sex automatically populated from the patient record when this is present in the patient record.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #17	A Yellow Card **MUST** be automatically populated with reporter name, address, telephone and email from the information held within the system.	A Yellow Card is automatically populated with reporter name, address, telephone and email from the information held within the system.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #18	All current repeat medications and any discontinued repeat or acute medication prescribed to a patient in the three months prior to the date of the Yellow Card creation date **MUST** be populated using dm+d entries, using the most detailed term level available (AMP>VMP>VTM>Active substance).	All current repeat medications and any discontinued repeat or acute medication prescribed to a patient in the three months prior to the date of the Yellow Card creation date are populated using dm+d entries, using the most detailed term level available (AMP>VMP>VTM>Active substance). For any repeat medications, this is limited to one entry with the initiation date.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria	A user **MUST** also be able to enter medicines entered using free text where dm+d cannot provide a suitable term.	The system enables the user to enter suspect and concomitant medicines using free text when dm+d cannot provide a suitable

#19		term.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #20	The user **MUST** select one or more medicines to indicate a suspicion of having caused (i.e. may have caused) the adverse drug reaction.	The system enables the user to select one or more medicines to indicate a suspicion of having caused (i.e. may have caused) the adverse drug reaction. The number of suspect medicines is not limited.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #21	A Yellow Card **MUST** include at one or more suspect reactions (coded using SNOMED CT concept IDs or MedDRA LLTs) and a reaction outcome for every reaction as selected by the user. (The list of outcome values is provided in DCB1582 electronic Yellow Card message fields and validations v3.0. Reaction outcome **MUST** be populated as 'unknown' if not known or is not available to the reporter)	A Yellow Card includes at least one or more suspect reactions (coded using SNOMED CT concept IDs or MedDRA LLTs) and a reaction outcome for every reaction as selected by the user. (It follows the list of outcome values is provided in DCB1582 electronic Yellow Card message fields and validations v3.0. Reaction outcome is populated as 'unknown' if not known or is not available to the reporter). The number of suspect reactions is not limited to any number.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #22	An IT system **MUST** reattempt transmission if the webservice is not available: retransmission should be reattempted at least 3 times over an appropriate time period. This is expected to extend over a period greater than 24 hours and must take into account out-of-hours and weekend system downtime. If still unsuccessful, the problem should be written to the audit log and brought to the user's attention - this may be through adding an item to a work queue or by notifying a user, local administrator, or system administrator. The user should be advised to report using alternative methods.	The IT system can reattempt transmission if the webservice is not available: retransmission can be reattempted at least 3 times over an appropriate time period (over a period greater than 24 hours and takes into account out-of-hours and weekend system downtime). If still unsuccessful, the problem is written to the audit log and brought to the user's attention - this is through adding an item to a work queue or by notifying a user, local administrator, or system administrator. The user is then advised to report using alternative methods.
Standard Specification 2.0 document Page 23 section 6.3 Conformance Criteria #23	If an XML is rejected due to an error, the user **MUST** be made aware of this fact using a method appropriate to the system. This may be through adding an item to a work queue or by notifying a user, local administrator, or system administrator. The user should be advised to report using alternative methods.	If an XML is rejected due to an error, the user is made aware of this fact using a method appropriate to the system. This may be through adding an item to a work queue or by notifying a user, local administrator, or system administrator. The user is then advised to report using alternative methods.

4 Changes to the Impact of the Yellow Card Scheme

The table of safety issues which the MHRA have helped identify has been updated with more recent examples. The table now appears as follows:

Year	Medicine	Adverse Reaction	Resulting action or advice
September 2016	Posaconazole (Noxafil)	Tablets and oral suspension are not directly interchangeable	Strengthened product information warnings to clarify the oral solution cannot be substituted for the oral tablet, or vice versa, at the same dose. The outer packaging was changed to better distinguish the difference in the two formulations. Drug Safety Update (DSU) article published
June 2016	Dexamethasone and Ritonovir	Drug interaction: increase the risk of systemic adrenal effects	Strengthened product information warnings detailing the drug interaction of systemic adrenal effects
April 2016	Natalizumab (Tysabri▼)	Progressive Multifocal Leukoencephalopathy (PML)	Strengthened product information warnings about PML including risk factors and risk minimisation measures. A direct healthcare professional communication (DHPC) was sent out to healthcare professionals to highlight the importance of monitoring through testing patients every 6 months to reduce risk of PML
December 2015	Cobicistat and fluticasone	Drug interaction: increase the risk of adrenal suppression	Strengthened product information warnings about the drug interaction increasing the risk of adrenal suppression after this was raised through the EU system. DSU article published
November 2014	Gaviscon Infant	Constipation	Strengthened product information warnings of constipation
October 2014	Proton Pump Inhibitors (PPIs)	Subacute cutaneous lupus erythematosus (SCLE), a nonscarring dermatosis that can develop in sun-exposed areas	Strengthened product information warnings of SCLE, including information for healthcare professionals and patients or carers about lesions especially in sun-exposed areas of the skin and accompanied by arthralgia. DSU article published

September 2014	Pregabalin	Abuse, misuse and dependence	Strengthened product information warnings regarding abuse, misuse and dependence
July 2014	Fentanyl patches	Life threatening harm from accidental exposure	Reminder of potential for life threatening harm from accidental exposure from swallowing or transfer to other individuals, particularly in children
March 2014	St John's wort (*Hypericum perforatum)* and hormonal contraceptives medicines and implants	Interaction resulting in reduced contraceptive effect	Reminder about herbal products that contain St John's wort and the interaction with hormonal contraceptives
September 2013	Filgrastim and pegfilgrastim	Life-threatening capillary leak syndrome (CLS)	Precaution to monitor patients and healthy donors for signs and symptoms of CLS, and give standard symptomatic treatment immediately if symptoms occur
Aug 2011	Lei Gong Teng (*Tripterygium wilfordii*)	Risk of serious side effects	Healthcare professionals are asked to remain vigilant and advise anyone currently using this product to stop taking it
Jan 2011	Sitaxentan (Thelin)	Hepatotoxicity	Worldwide withdrawal from the market

5 Changes to the Mapping of SNOMED CT to MedDRA terms and dm+d to MHRA drugs dictionary section

This section has been updated to include details of the mapping project the MHRA have initiated to map dm+d terms to the MHRA drugs dictionary and to update the wording in relation to MedDRA mapping project. The section is now as follows:

'Under European pharmacovigilance legislation, medical terms coded into E2B ICSRs transmitted between regulators and the pharmaceutical industry must use MedDRA. Use of MedDRA is almost solely for transmission of adverse drug reaction reports for pharmaceutical regulatory purposes. As MedDRA is therefore not used in clinical systems or elsewhere in the NHS, this standard specifies that medical terms in electronic Yellow Cards should be coded using SNOMED CT concept IDs.

Dm+d is the NHS dictionary of medicines and devices used in clinical systems. The MHRA has its own drugs dictionary. The MHRA is expecting to receive increasing volumes of reports from clinical systems, in these reports the drugs may be identified using the names from any of the three levels of the dm+d dictionary. It was identified that the dm+d drug terms were not compatible with MHRA drugs dictionary terms and would require manual population of the drug terms.

The MHRA has undertaken a process to build up a mapping between both SNOMED CT concept terms and MedDRA lower level terms and dm+d terms and MHRA drugs dictionary terms for Yellow Cards received from clinical systems. **These mappings are for MHRA internal use only.**

SNOMED CT mapping project

A set of principles were drafted for clinical classification cross-mapping for the UK edition of SNOMED CT, however no specific guidelines or principles on mapping of terminology to terminology were available. The MHRA performed a mapping for the most commonly coded MedDRA terms (for example the 1000 most frequently used terms). A representative from the MedDRA maintenance organisation, MedDRA MSSO, monitored this process.

dm+d mapping project

A mapping of over 135,000 medicinal terms from the dm+d dictionary to the MHRA's Drugs Dictionary was created to enable automatic processing of these reports and standardise coding practices. As the MHRA drugs dictionary is unique there were no specific guidelines in place however as with the SNOMED CT mapping project, a set of principles were drafted and data validated internally.

Once these initial stages were completed an internal process was developed to convert SNOMED CT codes into MedDRA LLT codes and dm+d terms into MHRA drugs dictionary terms before processing through the MHRA pharmacovigilance database. Yellow Cards received where the codes/terms have not been mapped fall into a staging area. This area is monitored on a daily basis by a team of Signal Assessors who perform coding of adverse drug reactions and Yellow Cards on a daily basis. Once a suitable term is selected, it is stored as a mapping for any future Yellow Cards.

In order that no information is lost at any mapping stage the original term names (from the terminology used in the clinical system) are collected in the Yellow Card message.

A quality audit process is being introduced to ensure mapping of terms between SNOMED CT and MedDRA/dm+d and MHRA drugs dictionary are appropriate.'

6 Minor corrections, amendments and updates

The following minor word changes have been made to sections of the reissued Specification to correct grammatical or typographical errors, amend the tense/wording to reflect the passage of time or to update current figures/processes.

- All references to the email address www.mhra.gsi.gov.uk and pharmacovigilance@mhra.gsi.gov.uk have been changed to remove the 'gsi'. They now read as www.mhra.gov.uk and pharmacovigilance@mhra.gov.uk.

- The MHRA website has been updated to https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency throughout the document.

- Minor grammatical and typographical errors have been corrected, where identified, for example removal of duplicated full stops.

- Section 2: 'Purpose', the last paragraph has been amended to include an up to date statistic 'In 2016, over 20% of directly reported Yellow Cards were received via SystmOne.

- 'Section 3: 'Background', the last paragraph has been amended to acknowledge the change in Yellow Card reporting (in terms of figures). The paragraph has been updated to show that the Scheme has been running for over 50 years, has received over 800,000 UK reports and currently receives approximately 40,000 Yellow Card reports each year.

- Section 3.1: 'ADR Reporting as a Professional Responsibility', the website for the location of Yellow Cards has been updated to https://yellowcard.mhra.gov.uk.

- Section 3.1: The relevant guidance links have been updated to reflect the current guidance from the professional bodies. The link to the British Medical Association has been removed as this guidance no longer exists.

- Section 3.3: 'Improving Reporting of Adverse Drug Reactions', the first paragraph has been updated to correct the passage of time. The graph has also been updated to keep it up to date. The second paragraph has been amended to correct the use of the 'data' to singular. The second to last paragraph has been updated to reflect the latest reporting statistics "By the end of 2016, 40% of GP practices had electronic Yellow Card functionality implemented and it is making reporting quicker and simpler. This has increased the number of Yellow Card reports received by the MHRA from practices. GPs have once again become the cornerstone of the Yellow Card Scheme accounting for 30% of all direct healthcare professional reports (data shown above). It is estimated that implementation in all of GP practices will result in further 5,000 reports each year." In the final paragraph the hyperlink has been corrected.

- Section 5: ‘Concept of Operation’ the last sentence has been amended as follows “Other existing reporting routes require manual completion of a form for either posting or electronic transmission.”

- Section 5.1: ‘Confidentiality’ has been updated in light of changes of MHRA internal processes. The second and final paragraphs are now as follows:

  “The MHRA meets current Government requirements and standards for management of security risk across its network to ensure sensitive data is protected adequately. It is externally audited and approved for connection to the Public Services Network.”

  “Under the agreement of its directors and DH the MHRA applies the Cabinet Office Security Policy Framework (SPF) to its security controls and policies, which are also aligned to ISO270001[1]. Its security policy has been agreed and approved by the MHRA Directors. The MHRA complete a security return each year which is reviewed by the security team at the DH and accepted by the Cabinet Office. Under the SPF the MHRA operates a system of Information Asset Ownership and governance to manage information risk. The CEO, Dr Ian Hudson, is the Caldicott Guardian for the MHRA; the senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. The Guardian plays a key role in ensuring that the organisation satisfies the highest practicable standards for handling patient identifiable information.”

- Section 5.3: ‘Terminologies’, the second paragraph has been updated to replace NHS Connecting for Health with NHS Digital.

- Section 5.5: ‘Typical workflows’, point 3 has been amended to align the wording of data elements with the rest of the document.

- Section 9: ‘Maintenance Plan-updating the E2B(R2) International Standard’, has been amended to make it up to date. The final three paragraphs are now as follows:

  “The standards have been published as international standards and will be implemented for transmission of adverse drug reaction reports in the near future. However, E2B(R2) will continue to be used for some years, allowing a transition period so that pharmaceutical companies and regulators are able to update their databases and messaging to use E2B(R3).”

  “Although the standard uses HL7 messaging which is already used for many applications in the NHS, using E2B(R3) as the basis for electronic Yellow Card reporting will introduce a significant delay. This is

[1] http://www.27000.org/iso-27001.htm

considered a significant disadvantage as a standard for electronic Yellow Card reporting will make a significant step in improving access to and ease of Yellow Card reporting. In addition, experience of use of the new standard in adverse drug reaction reporting is currently limited and this introduces additional risks to the project."

"The MHRA will monitor the implementation of E2B(R3) and make a decision on updating the electronic Yellow Card reporting standard once usage is more firmly established."

- The Glossary section has been moved from section 11 to the beginning of the document.

