Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DCB1582 Amd 16/2017 Electronic Yellow Card Reporting

Implementation Guidance

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.

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Contents

Amendment History:

Version	Date	Amendment History
0.1	15/08/2017	Draft version 1
1.0	14/09/2017	Updated in response to SME feedback

Approvals:

This document requires the following approvals:

Name	Organisation	Date	Version
Bhavini Vyas/Becky Owen	MHRA	14/09/2017	1.0

1 Overview

The Medicines and Healthcare products Regulatory Agency (MHRA) collects reports of suspected adverse drug reactions (ADRs) via the Yellow Card Scheme. Yellow Card reporting is already an established reporting system and is part of healthcare professional practice. There is a well-documented need to address under-reporting of adverse drug reactions and the electronic Yellow Card Standard helps to enable this. The MHRA provide a source of information on potential drug safety issues allowing the agency to take regulatory action to protect public health. The electronic Yellow Card Standard defines a method for submitting Yellow Card information electronically through clinical systems.

The Standard applies to NHS organisations where healthcare professionals contribute to the MHRA Yellow Card Scheme and their IT system suppliers. It aims to reduce burden on the healthcare professional by allowing them to populate the majority of the Yellow Card submission from the patient's electronic record.

Healthcare professionals are asked to submit Yellow Card reports if they have a suspicion that the drug caused the ADR. Causality does not have to be proven.

For established medicines and vaccines, healthcare professionals should report all serious suspected ADRs even if the effect is well recognised. This is particularly important for reactions occurring:

- In children
- People aged over 65
- To biological medicines
- Vaccines
- In association with delayed drug effects and interactions.

For drugs displaying the inverted black triangle symbol (▼) all suspected ADRs should be reported.

2 Scope of the Standard

The Standard is for providers of NHS care or treatment, 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:

- Patient
- Parent/Carers
- Consumer/Non-healthcare professional

The Standard excludes medical device incident reporting, reporting of adverse events or reactions to blood or blood components, defective medicine reporting, and reporting of medication errors where no harm occurs.

3 Key documentation

In order to implement the Electronic Yellow Card functionality successfully you will need to refer to the following documents:

Document Reference	Name
DCB1582 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

4 Purpose

This document is intended to provide guidance on the implementation of the DCB1582 Electronic Yellow Card reporting specification. It specifies roles and actions to take and details technical guidance needed to facilitate successful implementation and use of the Standard. It is broken down to satisfy two audiences:

1. Those organisations/system suppliers that **have** previously implemented the ISB 1582 Electronic Yellow Card reporting specification i.e. existing users.
2. Those organisations/system suppliers that **have not** yet implemented Electronic Yellow Card functionality via the ISB 1582 specification i.e. new users.

5 Checklist for Successful Implementation

These stages/guidance will aid the implementation of the electronic Yellow Card Standard.

- Initiation discussions with MHRA
- Technical specification documents
- Access to Yellow Card webservice
- Testing functionality
- Piloting and rollout of the functionality
- Training users

5.1 Initiation Discussions with MHRA

Previous experience and feedback from electronic Yellow Card integrations has suggested that IT system suppliers making initial contact with the MHRA before development of the integrated Yellow Card functionality could be beneficial.

- During these discussions, it is useful to run through the requirements to ensure full understanding and to deliberate any foreseen issues.
- It will allow for the MHRA to allocate appropriate resource to testing and feedback of the functionality so that timelines can be adhered to.
- A demonstration of the current system can be shown. It could help identify where functionality is best placed.
- MHRA will provide login details for test and production webservice environments.

These discussions are applicable to both audiences mentioned in section 4.

5.2 Technical Specification

Yellow Card messages are based on the ICH E2B(R2) Individual Case Safety Report international Standard[1].

Successful transmission of information into the Yellow Card webservice is dependent on the xml message meeting validation rules and parsing against the Document Type Definition (DTD). It is a requirement that all data fields **MUST** meet data validation requirements. Details of the message field list, validations and list of values can be found in DCB1582 electronic Yellow Card message fields and validations v3.0.

An example of a valid xml message can be found here ExampleICSR v3 0.xml. An example of a failed xml message can be found here ExampleICSRfail v3 0.xml.

The message must be encoded using either the ISO-8859-1, UTF-8 or UTF16 character-sets.

[1] http://www.ich.org/products/electronic-standards.html

Yellow Card messages are transmitted only in one direction - from the clinical system directly to the MHRA. There is no automatic process for nullification of Yellow Card reports. If necessary, any such action would be handled manually through contacting the MHRA.

Each Yellow Card report must have a unique safety report ID (GB-MHRA-XXX<globally unique reference number>). The MHRA recommend adding a site code to the unique reference so that safety report IDs are identifiable by site. This ensures different user sites do not overwrite the unique reference number count.

The change specification documents the changes made to requirements, message fields and validations spreadsheet and example ICSRs. Therefore, it is important that both new and existing users follow the updated technical guidance.

5.3 Yellow Card Webservice Guidance

The EHR service is a Standard SOAP 1.2 xml webservice over https (port 443).
The wsdl for the service can be found at:
https://ehr-services.mhra.gov.uk/v2/SubmissionService.asmx?WSDL

Before testing can begin contact needs to made with the MHRA to receive login details for both the test and production. Only one username and password is provided per system provider. Submissions of data sent without correct username and password authentication will not receive a response nor will they be processed by the webservice. This is applicable for new users only.

Contact should be via pharmacovigilanceservice@mhra.gov.uk, or call 020 3080 6764.

5.4 Testing

An appropriate test plan should be in place regardless of whether Yellow Card functionality is already integrated within the clinical system. Suppliers are expected to follow the normal process of documenting what testing will be performed.

System suppliers must provide a test environment that is reflective of a live GP practice or the relevant clinical organisation. User Acceptance testing must include both message creation and transmission using a series of scenarios, as well as showing that the front-end system functionality is present and user friendly.

For new users, test script scenarios are provided by the MHRA to test that the Yellow Card functionality is triggered appropriately. The specification details clinical scenarios of when a yellow Card should be triggered. An example of the typical workflow is also provided.

For existing users, test scripts can be used for regression testing. Emphasis should be on the additional message and validation fields and the change to requirement 23 if this has not already been implemented within the clinical system.

This end-to-end testing will require systems to transmit Yellow Card messages generated from within the systems using test data extracted or completed within the

system. Acknowledgments should be received to show that messages have been received successfully. Evidence of testing of suppliers' systems front end user interface will also be required as completed test scripts alongside the test xml files. These should show that the systems meet the requirements and conformance criteria defined in the specification document.

This is applicable to both new and existing users.

5.5 Pilot and Roll Out

Deployment of the Yellow Card functionality to live systems can only be made once testing has been formally signed off and agreed by the MHRA / GP Systems of Choice (GPSoC) supply manager, if applicable.

A pilot phase is required where electronic Yellow Card reporting should be enabled for a subset of GP practices and other clinical organisations using the specific supplier system which has had initial testing signed-off. The production Yellow Card webservice must be used as provided in the specification document. System suppliers should supply the MHRA with a roll out plan to ensure appropriate monitoring of the reports can be achieved.

System suppliers will need to obtain confirmation from the pilot sites that the functionality is working correctly and provide confirmation to their release managers.

As each System supplier completes the pilot process, a controlled rollout can commence to those GP Practices and other clinical organisations using that Supplier's Practice System.

The MHRA will continue to monitor the Yellow Card reports received and can provide report reconciliation to ensure that all reports submitted are being received. Submission of reports will be monitored for validation errors, correct population of data fields and any other issues that may arise. Communications between the MHRA and system suppliers should remain high during this time.

5.6 Training

Any user of the clinical system should be sufficiently trained on the changes to the system. New users should be trained specifically on the addition of Yellow Card Functionality.

Existing users should be made aware of the changes to the functionality. The changes to the original Standard are minor and the user may only notice the addition of drug dose/dose units to the front end of the clinical system.

The specification details clinical scenarios of when a Yellow Card should be triggered and an example of the typical workflow is also provided which can be used to demonstrate how the functionality works.

Guidance on how to use the functionality should be provided by the system suppliers. Input from the MHRA is always offered. The MHRA can provide

background information on the Yellow Card Scheme and guidance on what healthcare professionals should be reporting as well as any other ongoing training support needed.

IT trainers should be made aware of the functionality and any changes that are made to the system so that they can provide adequate information to users, both new and old. The benefit of this is to increase the understanding and emphasise the importance of the functionality.

5.7 Timelines

Since 31 December 2013, all applicable clinical system providers have been required to follow the Standard in full, and to meet all relevant requirements – compliance with the Standard should now be embedded into 'business as usual' with those with existing functionality.

Timelines for implementing changes are set out below for both new and existing users:

By 01 February 2018 new clinical system providers **MUST** have begun to prepare for implementation of the Standard or begun to prepare for the implementation of the changes to the standard if an existing user.

By 01 December 2018 all clinical system providers **MUST** be fully compliant with all aspects of the Standard.

6. Privacy

Yellow Cards do not include identifiable patient information and healthcare professionals do not need to seek the permission of a patient in order to send a Yellow Card.

The data submitted via a Yellow Card report is confidential and encapsulated into the MHRA's privacy policy. Details of this can be found here: https://yellowcard.mhra.gov.uk/privacy-policy/

System suppliers should make users aware of the information contained within this policy for example by providing access to it via guidance documents.