	EPS Release 2 NHS dm+d Requirement			
	Programme	*NPFIT*	**DOCUMENT RECORD ID KEY**	
	Sub-Prog / Project	EPS	**NPFIT-ETP-ECAP-0004.02**	
	Prog. Director	Ian Lowry		
	Owner	Mohammed Hussain	Version	2.0
	Author	Rob Gooch		
	Version Date	31/10/2011	Status	Approved

Electronic Prescription Service Release 2

NHS Dictionary of Medicines and Devices Compliance Requirement

ETP Programme

Amendment History:

Version	Date	Amendment History
0.1	19/10/2007	Initial Draft
0.2	07/11/2007	Comments from DLA Piper UK LLB
1.0	02/01/2008	Comments incorporated following review of v0.2
1.1	25/10/2011	Updated to align with dm+d compliance uplift
1.2	28/10/2011	Comments from MH and updated Top 2000 list
2.0	31/10/2011	Approved for publication

Reviewers:

Name	Signature	Title	Date of Issue	Version
Mohammed Hussain		EPS Clinical Safety Assurance Manager	31/10/2011	2.0
Stuart Abbott		Advanced Terminology Specialist	31/10/2011	2.0
Rob Gooch		Technical Architect	31/10/2011	2.0

External review by Richard Bonnar – DLA Piper UK LLP

Approvals:

This document requires the following approvals.

Name	Signature	Title	Date of Issue	Version
Ian Lowry		ETP Programme Director	31/10/2011	2.0

Document Status:

This is a controlled document.

This document version is only valid at the time it is retrieved from controlled filestore, after which a new approved version will replace it.

On receipt of a new issue, please destroy all previous issues (unless a specified earlier issue is baselined for use throughout the programme).

Related Documents.

These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
1	NPFIT-NPO-GEN-IP-0067	Glossary of Terms Consolidated.doc	Latest
2	NPFIT-ETP-EDB-0286	EPS GP CAP Procedure	Latest
3	NPFIT-ETP-EDB-0287	EPS Dispenser CAP Procedure	Latest
4	NPFIT-ETP-ECAP-0002	EPS Release 2 Clinical Assurance	Latest

Glossary of Terms

Acronym		
ISB	Information Standards Board	The NHS Information Standards Board provides an independent mechanism for the assurance and sign off of information standards for use in the NHS (England).
VMP	Virtual Medicinal Product	A VMP is an abstract concept representing the properties of one or more clinically equivalent Actual Medicinal Products, where clinical is defined as relating to the course of a disease.
VMPP	Virtual Medicinal Product Pack	A VMPP is an abstract concept representing the properties of one or more quantitatively equivalent Actual Medicinal Product Packs (AMPP's).
AMP	Actual Medicinal Product	An AMP is a single dose unit of a finished dose form (unless the product is presented as a continuous dosage form), attributable to an identified supplier that contains a specified amount of an ingredient substance.
AMPP	Actual Medicinal Product Pack	An AMPP is the packaged product that is supplied for direct patient use or from which AMP's are supplied for direct patient use. It may contain multiple components each of which may or may not be an AMPP in their own right.

Contents

1 Introduction

The dm+d is undergoing the process of becoming an ISB standard. Until that process completes the position of NHS Connecting for Health (NHS CFH) is that a dm+d implementation should be achieved through the integration of all relevant detail from the distributed dm+d data into the system's medicines and devices database.

However NHS CFH recognises that an integrated dm+d solution could cause system suppliers complications when other clinical terminologies, such as those for decision support, are also in use. Therefore the concept of allowing a mapped solution has been accepted as an interim measure.The NHS CFH position with regards the responsibility for any adverse incident arising because of an inaccurately integrated dm+d item the part of a system vendor or their subcontractor remains as has been previously stated: NHS CFH will not validate or underwrite the accuracy of any dm+d mapped solution (Reference NHS dm+d disclaimer – Appendix 3)

NHS CFH will however continue to perform an assurance role to satisfy itself that clinical systems developed by suppliers meet its patient safety requirements.

This involves the successful completion of the Common Assurance Process (CAP) [2][3] and of the EPS release 2 clinical assurance process [4].

This will entail reviewing and approval of system design, testing and implementation plans for patient safety and end to end message testing across a series of test scenarios and occasional spot checks. This does not imply any interrogation or audit of the underlying mapping or direct embedding of dm+d in the system, which remains the suppliers responsibility.

In summary therefore, the maintenance, validation and medico-legal responsibility for the integration of dm+d into an implemented system rests with the supplier of that system.

2 Purpose

The purpose of this document is to set out the compliance requirements for system suppliers with regards to the use of dm+d in their systems. By reading this document they will understand the expectation NHS Connecting for Health have in the use and application of dm+d within their systems. In respect of this suppliers will be expected to complete a ‘Statement of Compliance’ (Appendix 1) in which they will state their level of conformity to this compliance requirement.

3 Scope

The scope of this document is to set out the NHS CFH requirement with respect to a supplier’s use of NHS dm+d within EPS R2 systems. It outlines the assurance role of NHS CFH in defining the requirement for supplier compliance for the suppliers of EPS compliant prescribing and dispensing systems and setting out the requirement of NHS CFH to define one to one mappings.

Suppliers are required to ensure ongoing maintenance, update and progressive mapping (where required) to dm+d, to assure all mapping with the supplier’s own systems and to document adherence to the published compliance requirement on an ongoing basis according to common assurance requirements.

The actual content of databases used is specifically beyond the scope of this document.

4 Basic Assumptions

It is assumed for the purposes of this document that the supplier either

- Integrated use of dm+d through the creation of relevant detail taken directly from the distributed dm+d data

Or

- Operates a recognised approach to drug mapping acceptable to NHS CFH.

And

- Can demonstrate a suitable update mechanism to update terminology changes from a recognised dm+d source to end users in a timely manner in line with published EPS requirements.

5 EPS dm+d Primary Care Requirement

It is the NHS CFH intent that dm+d is integrated within the clinical system, through the creation of relevant detail taken directly from the distributed data. However it is understood that some system suppliers will map the dm+d to other clinical terminologies used within the system. It is anticipated that the percentage of items required for mapping will increase over time until either 100% of dm+d prescribable concepts are directly mapped or dm+d is used in a fully integrated system

Suppliers must provide a statement of compliance as to which level they have achieved for their product and version:

1. Confirm that they integrate dm+d through the creation of relevant detail taken directly from the distributed dm+d data ie with no mapping or;
2. Confirm that they can map to all 95% of the most commonly used items as defined by NHS CFH. This figure of 95% currently represents just over 2000 items, which are attached as dm+d compliance requirement 2011 (Appendix 2). Mapping is defined as a direct, one-to-one and semantically interoperable match. The VMP and AMP concepts listed in the spreadsheet 'dm+d mapping requirement 2007' must be mapped to as a minimum. (In addition, those suppliers who require the use of the VMPP and/or AMPP concepts are required to map, as a minimum, those concepts related to the medication items defined within the standard) and;
3. Where all of the products detailed in dm+d requirement 2011 cannot be mapped to, state how many of the items can be mapped. For each item that cannot be mapped to (for whatever reason), the supplier shall provide full details as to why this is not possible and an action plan including delivery dates on how they intend to address the issues identified.

6 NHS dm+d Assurance

As part of the Clinical Assurance of the Electronic Prescription Service (EPS) Release 2, suppliers are required to provide a statement of their compliance with the EPS dm+d requirement within their Patient Safety Assessment/Hazard Log as part of the Common Assurance Process. The Statement of Compliance is attached as appendix 1.

NHS CFH will define the requirement for supplier compliance and will, with appropriate notice periodically update and publish the compliance requirement.

NHS CFH will also issue guidance, as required, to assist suppliers in meeting the requirement.

7 Documentation

Documentation will be stored within FileCM.

8 Appendix 1

Statement of Compliance:

EPS Statement of Compliance 2011.doc

9 Appendix 2

dm+d requirement 2011:

20111101_Top2000.xlsx

10 Appendix 3

NHS dm+d disclaimer:

Pending the implementation of a standard, the current position of NHS Connecting for Health (NHS CFH) is that integrated use of dm+d should be achieved through the creation of all relevant detail within a system's medicines and devices database taken directly from the distributed dm+d data. However, in recognising the issues faced by certain system vendors the concept of allowing a mapped solution has been accepted.

However, the NHS CFH position with regards the responsibility for any adverse incident arising because of an inaccurately mapped or integrated dm+d item on the part of a system vendor or their subcontractor remains as has been previously stated: NHS CFH will not validate or underwrite the accuracy of any dm+d solution.

NHS CFH can and will only perform an assurance role to satisfy itself that the implementation of NHS CFH conformant messages meets its own patient safety requirements. This will entail reviewing and signing off implementation plans for patient safety and end to end message testing across a series of scenarios and occasional spot checks. This will not however imply any interrogation or audit of the underlying integration of dm+d into the system, which remains the suppliers' responsibility.

In summary therefore, the maintenance, validation and medico-legal responsibility for the mapping or integration of dm+d into an implemented system rests with the supplier of that system.