Report on the responses to the

Consultation on Monitored Dosage Systems Draft Standards

December 2014

Contents

About the Pharmaceutical Society of Northern Ireland

1.1 The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

1.2 Our primary purpose is to ensure that practising pharmacists in Northern Ireland are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

1.3 It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

- setting and promoting standards for pharmacists' admission to the register and for remaining on the register;
- maintaining a publicly accessible register of pharmacists, and pharmacy premises;
- handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

About the Consultation

1.4 A Monitored Dosage System (MDS) is a medication storage device that aids medicines adherence to individual patients.

1.5 The preparation of a MDS device involves authorised pharmacy staff repackaging and dispensing prescribed medication into a storage device in order to assist patients in the day-to-day management of their medicines and in the adherence to their prescribed medicines.

1.6 MDS provision aims to support patients to live independently in their own homes.

1.7 For pharmacies providing MDS it is essential that their systems are robust and that quality assured processes are in place to ensure that the assembly and supply of medicines in a MDS device is as accurate and safe as possible

1.8 The Pharmaceutical Society NI produced draft standards with the primary focus of improving quality and safety in MDS provision by identifying the processes and systems required by community pharmacies in order that the supply of MDS is safe and appropriate to patients.

Consultation Engagement

1.9 **Correspondence with key stakeholders**: All registrants and key stakeholders were emailed and details of the consultation with instructions on how to respond.

1.10 **Website:** The consultation document was available to download from the website along with a response form.

Purpose of report – approach and analysis

2.1 This report provides a summary of the responses to the consultation on draft standards in MDS provision held from 18 June 2014 to 10 September 2014.

2.2 The consultation document was based on four questions with space provided for respondents to make further comments on the proposed standards. The analysis primarily summarises general qualitative themes, responses and issues - highlighted areas of agreement, and diversity of opinion.

2.3 Due to the relatively small response rate a brief qualitative analysis of responses to questions is provided and a breakdown of responses by individuals/organisations is provided in appendix A.

2.4 No differential weighting was given to responses, and all responses were read and considered. Comments and points from individuals were considered alongside the views of organisations. Where the views of a particular organisation were considered to be particularly relevant to a question or issue this has been highlighted in the report.

2.5 In the report, comments and direct quotes are attributed to the grouped consultee category to which they fit i.e. individual pharmacist. With regards to organisations, we have in most instances directly attributed comments/quotes.

Consultation document

3.1 The consultation document outlined and explained the ten standards[1] that would be expected of a pharmacist providing a MDS service. Consultees were asked the following questions and were provided with space to make further comments on each question and in general.

1. **Are there any standards that require further clarification?**

   Yes No Unsure

2. **Do you think any additional standards are necessary?**

   Yes No Unsure

3. **Do you think there are any standards which should be reworded or removed?**

   Yes No Unsure

4. **Do you have any further comments on the standards?**

[1] Please see Appendix B for an outline of the ten proposed standards.

Yes No Unsure

Respondents

3.2 The Pharmaceutical Society NI received 13 responses. Four responses were made in an individual capacity and nine were made on behalf of an organisation. Of the responses made on behalf of organisations, two were from HSC organisations, three were from pharmacy representative bodies, one was from another regulator and three were private organisations (one being a provider of healthcare services to the NHS). Three of the individual responses were made by pharmacists and one was from a community pharmacy owner[2].

Main findings

3.3

- **11** consultees thought that the standards required further clarification, (eight organisations and three individuals).
- **Eight** consultees thought that no additional standards are necessary (five organisations and three individuals).
- **Nine** consultees thought there were standards which should be reworded or removed (seven organisations and two individuals), one consultee was 'unsure'.
- **Nine** consultees had further comments on the standards (seven organisation and two individuals).

Table One

Question 1: Are there any standards that require further clarification?		
Yes	**No**	**Unsure**
11 (85%)	2 (15%)	0 (0%)
Question 2: Do you think any additional Standards are necessary?		
Yes	**No**	**Unsure**
5 (38%)	8 (62%)	0 (0%)
Question 3: Do you think there are any standards which should be reworded or removed?		
Yes	**No**	**Unsure**
9 (69%)	3 (23%)	1 (8%)
Question 4: Do you have any further comments on the Standards?		
Yes	**No**	**Unsure**
9 (69%)	4 (31%)	0 (0%)

3.4 From examination of the responses, it is clear that the majority of consultees had issues with the draft Standards. Two broad and interlinked themes can be

[2] Please see Appendix A for full breakdown of respondents.

extrapolated from the responses. Firstly, it was considered the standards are largely covered by existing legislation, regulations and standards. Secondly, the proposed standards did not provide enough detail to adequaltey address all of the issues relating to public safety pharmacists and other Healthcare professionals have when it comes to using MDSs.

Responses to Question one: Are there any standards that require further clarification?

4.1 11 consultees thought that the standards required further clarification, (eight organisations and three individuals). Two consultees did not consider any standards require further clarification –(one organisation and one individual response)[3].

Standard One -

The Responsible Pharmacist must ensure that standard operating procedures (SOPs) are written for each stage in the assembly and supply of medicines in the MDS device.

4.2 One individual pharmacist sought further clarification and guidance on what constitutes 'authorised staff', referred to in the preamble to Standard One.

4.3 The same respondent suggested that an SOP should be required to ensure the accuracy of the 'list' i.e. the contents of the MDS should be up to date and complete. They suggested one prescription may not have all the items a patient should be on; asking, how one can check for items which have been stopped.

4.4 Correspondingly HSCB in its response suggested that SOPs relating to patient consent could be incorporated into standard 10, concerning patients and carers being given appropriate advice. Stating it is "*useful to have an agreement between the patient and the pharmacy, which hospital staff could then have access to on hospital admission. Consent for this could be obtained from patient at initiation of MDS. This could include:*

- *a list of meds in the MDS and also all other meds supplied separately. This would help greatly with continuity of care.*
- *details of delivery, collections, how many weeks issued at a time etc*".

4.5 Celesio UK in its response requested further clarification on the requirement for patient consent to be obtained, and the mechanic that would be used to record this and clarity on what patients would be consenting to.

Standard Two –

The pharmacist must either have received a valid request from a prescriber or be in possession of a legally valid prescription before making a supply of medicine in the MDS device.

[3] No respondents made further comments with regards to Standard Four.

4.6 Five respondents sought further clarification on the term 'valid request from a prescriber'. For example in its response Community Pharmacy Northern Ireland (CPNI) stated*:*

"Further clarity is needed on what exactly "a valid request from a prescriber" refers to, in particular does request refer to medicine or a MDS request, this is important as recent guidance from HSCB to both pharmacy contractors and GPs made it clear that GPs cannot request MDS supply, such a decision can only be taken by the pharmacist providing service".

4.7 Another respondent asked if the current wording suggests that a request is a legal alternative to having a valid prescription?

Standard Three

The pharmacist must adhere to a written protocol when addressing changes to medication thus providing a clear audit trail.

4.8 The Pharmacy Forum stated that Standard Three needs clarification, in terms of the specific detail to be included in any protocol.

Standard Five

The pharmacist must ensure that only suitably trained and competent staff must be involved in the assembly, preparation and supply of a medicine in the MDS device

4.9 Three respondents sought further clarity on what constitutes a 'suitably trained' member of staff. Some made suggestions as to what that further clarification might be, for example, the South Eastern Trust stated that Standard Five "*should state: must involve pharmacist or ACT in assembly/checking of MDS and that all original packs be checked by pharmacist/ACT prior to preparation of MDS*".

Standard Six

The pharmacist must use their professional judgement on all medicines to be included in the MDS device to determine their suitability

4.10 The Pharmacy Forum highlighted the lack of information concerning the stability of Drugs, referencing that the removal of a medicine from the original packaging and repackaging into an MDS will often be an unlicensed use of a product. It sought more clarity on this issue with regards professional indemnity. An individual pharmacist noted the UKMI stability database as a reference point.

4.11 The same respondent also suggested a patient's individual circumstances should also be taken into consideration when making a decision to include/exclude a medication. And that in the circumstances of excluded medicine adequate information is effectively communicated to the appropriate person (patient/carer/care manager).

Standard Seven

Pharmacists must ensure that they label medicine supplied to a patient in a MDS device in accordance with the relevant legislation

4.12 Two respondents made reference to the need for pharmacists to adequately label on the MDS where additional medicines have been prescribed but are not included in the MDS.

4.13 A response made by individual pharmacists stated : "*this should also include 'labels should be separately spaced to allow their visibility.' If the patient receives medication which does not go into the MDS, a sticker should be added to the MDS, 'This patient is on other medicines not contained in this MDS' to alert professionals to this*".

Standard Eight

Pharmacists must ensure that a PIL is provided on each occasion a medicine is supplied to a patient in the MDS device or at appropriate dispensing intervals.

4.14 The Pharmacy Forum suggested that Standard Eight does not address MDS made up for a care home setting and sought further clarification on how PILS can be used in a care home setting. The SET asked if 'appropriate intervals' for supply of PILS needs to be defined further.

Standard Nine

The pharmacist must ensure that the patient's computer-held records and labels correspond with the details written on the patient's prescription and that a record is made on the Patient Medication Record (PMR) and any supporting documentation record of any changes to the patient's medicines recording who authorised the change.

4.15 A number of respondents outlined concern that this standard did not provide adequate clarity for pharmacists. For example Boots suggested that it should state that electronic patient records are equivalent to paper-based ones. An individual pharmacist stated that it should also include who initiated the MDS, the reason for this, if there was a formal assessment undertaken and provide care manager/key worker details.

4.16 CPNI raised specific concerns around the lack of clarity of the standard stating: "*It is not clear what exactly is required or expected within this Standard, for example, given that prescriptions are now scanned into most PMRs and these include details of the prescriber, would a scanned prescription record be sufficient or is a specific entry required to highlight a change"?*

4.17 CPNI went onto say: "*The explanatory paragraph may be somewhat confusing in that it suggested that the list of supporting documentation is "required" to be "recorded and retained" but then states "where available, for example". This does not provide clarity to pharmacists on exactly what is expected*".

4.18 The Pharmacy Forum also raised a concern that Standard Nine does not cover MDS supplied to a care home and the implications for MDS supplied to patients via delivery drivers.

Standard Ten

The pharmacist must ensure that the patient and/or their carer are given appropriate advice on the medicines supplied and on the safe use of the MDS device.

4.19 Again further clarification was sought on how the Standard might be used in a care home setting and with regards the couriered delivery of medicines.

Responses to question two: Do you think any additional standards are necessary?

5.1 Eight consultees thought that no additional standards are necessary (five organisations and three individuals). Five consultees thought that additional standards where necessary (four organisational and one indivdual response).

Information provision and sharing

5.2 A theme emerging from responses was that additional standards are necessary related to information provision and the sharing of information amongst health professionals related to MDS use.

5.3 For example the HSCB suggested that an additional standard be added to the communication section which states:

"Pharmacists should ensure that the patient's GP has been notified when they are assessed as requiring a MCA.

"Reason: GPs should have a record of an individual's MCA use and the name of their community pharmacy in the patient records to ensure that changes can be communicated to the pharmacist in a timely manner".

5.4 In a related manner an individual pharmacist stated that if a community pharmacist is placing medication on the MDS under any request/arrangement not involving the GP, the GP surgery should be made aware of this in writing. The respondent suggested that this will ensure the GP surgery will know to contact the pharmacy if any medications are stopped because the pharmacy may have a valid prescription for the stopped items.

5.5 The South Eastern Trust stated that: "*a standard patient record could be provided as part of the consultation standard, and maintained by the supplying pharmacy*. *This could be based on the agreed standards. It would allow everything concerning the MDS to be recorded, and be accessible to other health professionals. It would greatly improve communication when staff vary e.g. locums are present".*

5.6 HSCB suggested that an additional standard be added to the 'accountability/liability section regarding the suitability of the MDS/MCA to comply with legal requirements for labelling. HSCB highlighted several medication incidents reported to them where the labels were completely detached from the MCA or were not updated at each dispensing. Reports were also made where patients brought the wrong card/labels with their MCA on admission to hospital and incorrect medications prescribed.

Review of MDS provision

5.7 An additional suggestion from an individual pharmacist was that a patient receiving MDS should be reviewed annually to determine if the MDS use is meeting their needs and if it is appropriate to continue to supply medication in this manner.

Responses to question three: Do you think there are any standards which should be reworded or removed?

6.1 Nine consultees thought there were standards which should be reworded or removed (seven organisations and two individuals), one consultee was 'unsure'. Three consultees did not think there were any standards which should be reworded or removed.

Use of the term MDS

6.2 HSCB made some overarching comments about the standards and the consultation document in this section, in particular, it thought the term 'Multi-compartmental Compliance Aid, MCA, should be used instead of MDS, as the standards should apply to automated MCAs. It contended that the term is now used to encompass the use of automtated and sachet MCAs which are in use in some community pharmacise in Northern Ireland.

Overlapping Standards

6.3 HSCB also considered that Standards two, three and nine overlap as:

- Standard 2 refers to SOPs for medication changes and audit trail;
- Standard 3 refers to SOP for changes and audit trail;
- Standard 9 refers to record keeping & recording changes to patients medicine

6.4 HSCB suggested that standard two remains the same; e.g. elements of process to include in SOPs and that standard three is removed and the 'clear audit trail for medication changes' is incorporated into standard Nine about record keeping.

Existing legislation and standards

6.5 Boots also stated that: "*serveral of the standards make reference to complying with existing legisltation and guidance. Since pharmacists (and pharmacy owners) already have this duty, we do not think that it is necessary to state this again with this guidance. A general statement in the preamble that all releveant legislation and good practice should be complied with would be sufficient. This would allow several standards to be removed*".

Standard one : *The Responsible Pharmacist must ensure that standard operating procedures (SOPs) are written for each stage in the assembly and supply of medicines in the MDS device.*

6.6 Three respondents noted that the requirement for SOPs is already covered in existing legislation (The Health Act 2006 and Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008).

6.7 Two other respondents considered the list of elements SOPs should address under Standard one are incomplete.

6.8 For example, HSCB suggested the following elements be included:

- *Staff responsibilities*
- *Effective communication with all relevant parties*
- *Staff training*
- *Quality assurance process*
- *Assembly, labelling & supply*

6.9 RQIA outlined that its inspectors experience a wide variation regarding the management of MDS and would therefore expext SOPs to detail the following in relation to the listed elements:

2. Protocol to address medication changes – with a clear audit trail*: need to state roles and responsibilities; who is responsible for managing changes after hospital discharge, GP visits, how does pharmacy know that prescription is current, how are records of medication changes maintained; how are medication changes from registered facilities managed; how are medication changes in multi-compartment MDS packs managed when a change occurs i.e. are they returned to the pharmacy by the customer/ registered facility?*

3. Assembly and Supply: *how are MDS stored in the pharmacy; are controlled drugs in MDS stored in the CD cupboard up to the point of collection; how far in advance should they be prepared?*

4. Advice and Information: this should specify that each medicine must be clearly identifiable in the MDS, especially if it is a multi-compartment MDS pack.

5. Patient Consent: *how is patient consent achieved at pharmacy level for people who live in registered facilities?*

Standard Two

The pharmacist must either have received a valid request from a prescriber or be in possession of a legally valid prescription before making a supply of medicine in the MDS device.

6.10 Boots referenced the fact that the requirement for a valid request from a prescriber or a valid prescription is a duty under the Medicines Act 1968 and Medicines Regulations 2012. CPNI stated it is a general requirement for the supply of all prescription medicines.

Standard Three

6.11 CPNI considered that the standard is already covered within Standard One, where it has been detailed as point 2 within the box detailing necessary SOPs.

6.12 RQIA considered that Standard Three should include details on who is responsible for informing pharmacists of any medication change, how the medication is received in the pharmacy and how the changes to multi-compartment compliance aids are made.

Standard Four

The pharmacist must ensure the dispensing area in the pharmacy is maintained in a good state of repair and is clean, tidy and uncluttered for the safe assembly of the MDS device.

6.13 CPNI, Boots and the Pharmacy Forum all considered that Standard Four is already covered within the Pharmaceutical Society NI's Standards for Registered Pharmacy Premises (2010).

6.14 Referencing the consideration that untidy dispensing areas can also contribute to inaccuracies and errors, the HSCB considered that the word 'accurate' should be added to the standard so that it reads: 'the safe and accurate assembly of MDS device'.

Standard Five

The pharmacist must ensure that only suitably trained and competent staff must be involved in the assembly, preparation and supply of a medicine in the MDS device.

6.15 CPNI considered that Standard Five already forms part of the Responsible Pharmacist Regulations.

6.17 RQIA noted that it finds practice regarding the management of medication changes varies and it has been evidenced that staff in registered nursing/residential homes have been expected to make changes to MDS. It considered that Standard Five should detail that the pharmacist is responsible for making changes to any MDS multi-compartment systems when a medication change has occurred.

Standard Six

The pharmacist must use their professional judgement on all medicines to be included in the MDS device to determine their suitability.

6.18 Boots considered that Standard Six is already covered by principle 4 of the Pharmaceutical Society NI's Code of Ethics which obligates pharmacist to exercise professional judgement in the interests of patients and public.

6.19 CPNI considered that Standard Six is covered sufficiently within the Pharmaceutical Society NI's Professional Standards and Guidance for the Sale and Supply of Medicines, referencing paragraph 1.7 of the document which states:

The removal of medicines from blister or foil packs only, where required, at the time of dispensing, to assist an individual patient. In so doing, the integrity of the medicine must not be impaired.

6.20 RQIA outlined that the view of its inspectors is that there is a wide variation of what is considered to be appropriate to include in a MDS, for example, Epilim tablets and aspirin dispersable.

6.21 CPNI outlined that in its opinion there is currently no readily accessible resource detailing stability of products outside of manufactuer's original packs and that if Standard Six remained, with the current lack of clear stability infomration a situation may arise where pharmacists withdraw the service to patients.

6.22 CPNI suggested the additional statement – "the decision on whether to include or exclude a medicine from a MDS device is soley reliant on the professional judgement of a pharmacist", be removed. However, a Pharmacy Owner welcomed the statement regarding professional judgement citing that in many cases the phramacist must balance the risk to the patient of them failing to receive the medication at all, if it is not included in the MDS device, with theoretical stability issues. The respondent further stated that the issue of carers refusing to give medication which is not contained in an MDS device has to be considered when trying to ensure the safety of the patient and their compliance.

6.23 HSCB suggested that the current wording of Standard Six implies a clinical check on suitability for the patient rather than a pharmaceutical assessment of suitability for inclusion in an MCA. It suggested the standard be changed to read:

"*The pharmacist must carry out a pharmaceutical asessment of all medicines to be included in the MCA to determine their suitability based on evaluation of the evidence*".

Standard Seven

Pharmacists must ensure that they label medicine supplied to a patient in a MDS device in accordance with the relevant legislation

6.24 Boots referenced the Human Medicines Regulations (Marketing Authorisations Etc) Regulations 2012, with regards to labelling issues. CPNI stated that Standard Seven

is common to all medicines and is already well covered within the PSNI's Professional Standards and Guidance for the Sale and Supply of Medicines. Whilst the Pharmacy Forum felt that tablet identification is a matter of good practise that should be covered by SOP and does not need to be in the Standards.

6.25 HSCB considered that this Standard should be moved to the 'process' section as labelling is part of the assembly process for the preparation of MDSs.

6.26 RQIA said that its experience is that community pharmacists dispense medicines in MDS systems which cannot be indentified due to similarlity with other medicines, with few community pharmacists supplying specific indentification of individual medicines.

Standard Eight

Pharmacists must ensure that a PIL is provided on each occasion a medicine is supplied to a patient in the MDS device or at appropriate dispensing intervals.

6.27 CPNI and Boots noted that this is already a basic legislative requirement within the Human Medicines 2012 Regulations.

6.28 A phramacy owner questioned the practicality of including a PIL each time a MDS decvice is provided as this can occur weekly or even daily and only one PIL is available per 28 pack of dispensed medicine. Additionaly they considered the wishes and direction of the patient/carer must be taken into account as most find it cumbersome and wasteful if PILS are delivered with each MDS service. The respondent stated: "*where appropriate these could be offered electronically so that a copy is permanently accessible*".

Standard Nine

The pharmacist must ensure that the patient's computer-held records and labels correspond with the details written on the patient's prescription and that a record is made on the PMR and any supporting documentation record of any changes to the patient's medicines recording who authorised the change.

6.29 CPNI considered that the general content of Standard Nine applies to all medicines, with standards already described within the Pharmaceutical Society's Standards and Guidance for the Sale and Supply of Medicines.

6.30 Boots considered that the Standard would benefit from being reworded as two or more sentences, whilst HSCB thought the supplementary list confusing as it describes records to be kept and some processes as examples.

6.31 One individual respondent questioned the need to record changes in the PMR – citing that if a paper trail is already in use, the PMR is of no additional benefit and often has limited space.

Standard Ten

The pharmacist must ensure that the patient and/or their carer are given appropriate advice on the medicines supplied and on the safe use of the MDS device.

6.32 CPNI and Boots both cited that the Standard is already contained with the Pharmaceutical Society NI's Professional Standards and Guidance for the Sale and Supply of Medicines.

6.33 HSCB considered that Standard Ten and the corresponding section 6.1 of the consultation document which refers to Counselling and Advice should be moved to the 'information' section which accompanies Standard Eight and the following points should be added to the list of advice for the patient/carer:

- *Discuss medicines that have not been included in the MCA e.g. not suitable or not available*
- *Discuss medicines that may have changed in appearance e.g. brand changes.*

6.34 The RQIA suggested a further supplementary point should be added regarding "*the need to inform the patient/carer/registered facility how medication changes are to be implemented .i.e what happens if the medicines are discontinued, a new medicine is added –how is the compliance aid amended"?*

Responses to question four: Do you have any further comments on the standards?

7.1 Nine consultees had further comments on the standards (seven organisation and two individuals).

Basic comments on proposals

7.2 A number of comments in this section refered to the general need for and efficacy of the proposed standards. A number of respondents questioned the need for new Standards altogether- suggesting guidelines might be more appropriate, whilst other respondents believed they needed to be clarified further with more detailed guidelines attached.

7.3 For example, the NPA stated:

"We do not believe that the production of additional standards is the best way to provide the support required. Existing standards cover the assembly and supply of medicines, be it original pack dispensing, broken bulk or MDS.

The draft standards lack the clarity and detail which pharmacy teams need to improve the assembly and supply of MDS. The NPA will provide detailed comments if required.

Any additional support should be given in the form of guidance which can cover the points raised in the draft standards in detail and include areas which have been omitted from the draft standards such as the checking the MDS trays.

We would like to point out that various UK pharmacy organisations have produced excellent guidance covering all aspects of the supply of MDS".

7.4 In a similar vein, CPNI, in its accompanying letter to the consultation stated it is:

'not sure that these actually constitute new Standards. What the current draft document does well is to describe how existing Standards and Regulations apply to MDS service provision. [I] believe pharmacy contractors would welcome a document which accurately summarises all of their obligations throughout the process, however, it is CPNI'S opinion that this would be more appropriately presented as a guidance document, rather than being conveyed as new standards".

7.5 CPNI also referenced the Royal Pharmaceutical Society's guidance document of July 2013 "*Improving patient outcomes - the better use of multi-compartment compliance aids*".

7.6 RQIA stated that: "*the proposed standards are too broad; more detail is required*" and "*that the proposed standards seem to be reliant on the production of SOPs to provide the detail without giving guidance on the contents of the SOPs*".

Using MDS in Primary care and residential settings

7.7 RQIA went on to outline the lack of clarity surrounding how MDS devices are used and administered in care homes and where responsibility for MDS use lies in such settings, *stating that:*

"Although it is recognised that there is little need for MDS in nursing or residential homes, these devices are widely used and their supply by community pharmacists should not compromise any other healthcare professional. For example a community pharmacist should not expect a registered nurse to manage dosage changes to the MDS.

On page 7 the sentence 'that aids medicines adherence to individual patients' is not applicable when medicines are administered by staff in registered facilities – MDS is widely used for this population but they are not included in the definition or proposed standards.

The proposed standards do not:

- *refer to the recently published NICE guidelines*
- *refer to registered facilities with regard to patient consent and overall management of MDS medicines*
- *refer to multi-compartment MDS packs*
- *acknowledge that liquid medicines are supplied in MDS*
- *detail who is responsible for making the medication change when a change has occurred and the compliance aid has already been delivered to the patient/registered facility*
- *Identify the different types of MDS in use – weekly compliance aids used in the community, multi-compartment or single compartment MDS used in care homes".*

7.8 RQIA went on to say that a communication strategy for the dissemination and implementation of the Standards would be welcome.

7.9 HSCB stated that although the consultation focussed on monitored dosage systems, these "*are part of a much wider issue of helping people to manage their own medicines-taking. It would have been helpful to discuss the scope of the standards with HSCB and others prior to engagement with all organisations to understand what the scope of standards should be*".

Layout of the document

7.10 HSCB stated that it found the document layout and numbering confusing and suggested using a standard template for each standard to assist readability. HSCB also suggested that Appendix 1 would benefit from an additional column on how this data could be collected by pharmacists prior to recording their audit result.

7.11 A number of respondents made specific points about individual standards in answer to question four.

Patient Safety

7.12 Boots stated that the stated purpose of Standard Three, of requiring pharmacists to follow written protocol (or standard operating procedure) should be stated as "to avoid errors" and/or "to improve or maintain patient safety", rather than just "providing a clear audit trail". Boots contended that an audit trail is a reactive method of assessing safety rather than a positive set of actions.

7.13 Boots also raised concerns regarding Standard Six, suggesting that the use of 'professional judgement' might lead to variations between different pharmacies and responsible pharmacists which might be confusing for patients.

7.14 Celesio UK raised concerns with regard to Paragraph 4.1 of the consultation document which deals with the suitability of medicines to be included in an MDS device, stating that *"there is also a role for the prescriber in making a decision on treatment as, even if a pharmacist has taken the decision to supply medicines in an MDS devices in line with their professional judgement and standard operating procedures, the stability of a medicine cannot be guaranteed as there is no control on storage environment, etc once it has left the pharmacy*".

7.15 Celesio UK also raised issues with Standard Nine seeking confirmation that any changes to medication would be made by the prescriber, and therefore not likely to be recorded in pharmacy. They also sought clarification on signing for an MDS device when collected and why this would be any different to collecting a normal prescription from the pharmacy. They also raised concerns at the ability of the pharmacist to identify informal carers or multiple carers to record their name.

Appendix A

	Respondents	Individual/Organisation type
1.	Gareth Peeples	Individual Pharmacist
2.	Catherine Graham	Individual Pharmacist
3.	Gillian Gracey	Individual Pharmacy Owner
4.	Jo Gribben and Caroline Johnston	Individual Pharmacists
5.	Boots	Private Organisation
6.	Celesio UK	Private Organisation
7.	Randalstown Community Pharmacies	Private Organisation
8.	Pharmacy Forum NI	Pharmacy Representative Body
9.	Community Pharmacy NI	Pharmacy Representative Body
10.	National Pharmacy Association	Pharmacy Representative Body
11.	Health and Social Care Board	HSC Organisation
12.	South Eastern Trust	HSC Organisation
13.	RQIA	Regulatory body

Appendix B

Standard 1

The Responsible Pharmacist must ensure that standard operating procedures (SOPs) are written for each stage in the assembly and supply of medicines in the MDS device

Standard 2

The pharmacist must either have received a valid request from a prescriber or be in possession of a legally valid prescription before making a supply of medicine in the MDS device

Standard 3

The pharmacist must adhere to a written protocol when addressing changes to medication thus providing a clear audit trail

Standard 4

The pharmacist must ensure the dispensing area in the pharmacy is maintained in a good state of repair and is clean, tidy and uncluttered for the safe assembly of the MDS device

Standard 5

The pharmacist must ensure that only suitably trained and competent staff must be involved in the assembly, preparation and supply of a medicine in the MDS device

Standard 6

The pharmacist must use their professional judgement on all medicines to be included in the MDS device to determine their suitability.

Standard 7

Pharmacists must ensure that they label medicine supplied to a patient in a MDS device in accordance with the relevant legislation

Standard 8

Pharmacists must ensure that a PIL is provided on each occasion a medicine is supplied to a patient in the MDS device or at appropriate dispensing intervals

Standard 9

The pharmacist must ensure that the patient's computer-held records and labels correspond with the details written on the patient's prescription and that a record is made on the PMR and any supporting documentation record of any changes to the patient's medicines recording who authorised the change

Standard 10

The pharmacist must ensure that the patient and/or their carer are given appropriate advice on the medicines supplied and on the safe use of the MDS device