Health and Social Care Board

Community Pharmacy Assurance Visit Protocol 17/18
Part I - Terms of Service & Service Specification Requirements

Contractor Number:	< completed by HSCB>	Confirm	Comments	Actions
Contractor Name & Address:	(as per current Pharmaceutical list): < completed by HSCB>	☐ Yes ☐ No		

Q1. Hours of provision of pharmaceutical services

Context
The pharmacy's "Contracted Hours" are those detailed in the Pharmaceutical List: http://www.hscbusiness.hscni.net/services/2053.htm
Community pharmacies must open during **all** of their agreed contracted hours. Any requests to change contracted hours should be submitted in writing to BSO detailing the proposed changes and the reason for the changes.

		Confirm hours	Comments	Actions
Contracted Hours	(as per current Pharmaceutical list): < completed by HSCB>	☐ Yes ☐ No		
Opening Hours (Commercial)	< completed by HSCB from declaration>	☐ Yes ☐ No		

Q2. Additional professional services - Practice leaflet

Context

Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997** http://www.hscbusiness.hscni.net/services/2539.htm the pharmacy contractor is required to produce a practice leaflet which should include:

1. A list of the pharmaceutical services which the chemist has undertaken to provide and for which his name is included in the pharmaceutical list;
2. The name, address and telephone number of the premises from which he provides those services and the hours in each day of the week during which he provides those services from those premises;
3. The arrangements made by the chemist to provide, or such arrangements as the chemist has made with any other chemist to provide, pharmaceutical services to any person who needs those services in an emergency or outside of the normal hours during which the chemist provides pharmaceutical services (For example, display of rota key, rota information on BSO website or in local press, details of NI direct website http://www.nidirect.gov.uk/choosewell, contact details of local GP OOH centres); and
4. The procedure by which any person may comment upon the provision of pharmaceutical services provided by the chemist.

Question		Comments	Actions
Was the pharmacy's practice leaflet submitted with the annual assurance declaration? < completed by HSCB>	☐ Yes ☐ No		
Does the leaflet include? • Name, address & telephone number. • List of pharmaceutical services • Opening hours • Out-of-hours arrangements • Complaints/comments information	☐ Yes ☐ No		
Is the practice leaflet on display in an easily accessible part of the pharmacy?	☐ Yes ☐ No		

Guidance Notes

Template leaflets produced for use by community pharmacy in other regions of the UK may contain references which are not relevant to Northern Ireland e.g. NHS, Primary Care Trusts, Health Authorities. Please ensure the terminology used in your leaflet is appropriate for Northern Ireland.

To comply with Terms of Service, the Pharmaceutical Services listed should only be those provided in the premises named on the leaflet. Terms of Service states, “A list of the pharmaceutical services which the chemist has undertaken to provide and for which his name is included in the pharmaceutical list”. It is not acceptable to have one leaflet to cover services provided across a group of pharmacies which are not provided in the individual named pharmacy. Provision of oxygen is a pharmaceutical service which should be included in the leaflet if listed in the pharmaceutical list.

Q3. Additional professional services – Health Promotion Leaflets

Context
Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997** http://www.hscbusiness.hscni.net/services/2539.htm the pharmacy contractor is required to display health promotion leaflets.

Question		Comments	Actions
Are there up to 8 health promotion leaflets on display?	☐ Yes ☐ No		

Q4: Additional Professional Services - Record keeping

Context

Pharmaceutical Services Regulations (NI) 1997 Terms of Service requires pharmacists claiming Additional Professional Services payments to 2(c) keep records in connection with drugs supplied to any person -

(i) who is aged 60 or over; or

(ii) who, in the opinion of the chemist providing the drug, is likely to have difficulty understanding the nature and dosage of the drug provided and the times at which it is to be taken, in circumstances where the nature of the drug is such that, in the opinion of the chemist providing it, the same or a similar drug is likely to be prescribed for that person regularly on future occasions.

HSCB Dispensing Service Specification 3.2 requires that the pharmacy maintains a record of all medicines and appliance supplied to facilitate continued care of the patient.

Pharmaceutical Society of NI's The Code, Standard 2.3 requires pharmacists to record, store and process data clearly and accurately. Standard 2.3.4 requires all records to be kept securely and in an organised manner and for the appropriate period of time.

Question	Confirmation/ additional information	Comments	Actions
What is the process used for keeping records of all HSC prescriptions dispensed?			

Guidance Notes

During the visit a series of questions may be asked and requests may be made to see records that are required to be kept, where these may be disclosed without breaching confidentiality.

Department of Health's Good Management, Good Records Section M, outlines the requirements for retention and disposal of community pharmacy held records: https://www.health-ni.gov.uk/articles/disposal-schedule-section-m

Q5. Complaints procedure

Context
Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997** http://www.hscbusiness.hscni.net/services/2539.htm , every pharmacy is required to have in place a complaints procedure which includes:

- Provision of information within the pharmacy about the complaints procedure
- A specified person who deals with complaints
- Management of complaints - all complaints must be:
    - Recorded in writing
    - Acknowledged within 3 working days
    - Properly investigated *and*
    - A written summary of the investigation and conclusions provided to the complainant within 10 working days.
- Keeping records of all complaints and associated correspondence

Question		Comments	Actions
Was the pharmacy's complaints procedure submitted with the annual assurance declaration? < completed by HSCB>	☐ Yes ☐ No		
Is there a specified complaints contact? (name or job title)	☐ Yes ☐ No		
Does the procedure include the required steps for the management of complaints? • Recorded in writing • Acknowledged within 3 working days • Properly investigated *and* • A written summary of the investigation and conclusions provided to the complainant within 10 working days.	☐ Yes ☐ No		

• Keeping records of all complaints and associated correspondence			
Are complaints dealt with within the required timescales detailed in Terms of Service?	☐ Yes ☐ No		
Is there information within the pharmacy about the complaints procedure? e.g. HSCB template leaflet or poster	☐ Yes ☐ No		

Guidance Notes

Resources to help support the management of complaints are available on the BSO website http://www.hscbusiness.hscni.net/services/2659.htm
These include:

- a HSCB template poster and leaflet on complaints procedures
- a link to e-learning on the management of complaints

Q6. MUR service – consultation area requirements

Context

The MUR service specification (http://www.hscbusiness.hscni.net/services/2427.htm) specifies that the part of the pharmacy used for the provision of MURs must meet the following requirements for consultation areas:

- the consultation area should be where both the patient and the pharmacist can sit down together
- the patient and pharmacist should be able to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)
- the consultation area should be clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy

Current MUR Activity

Pharmacy contracted to provide the MUR service Yes / No

No of Initial Reviews: Latest Quarter <insert dates> <number inserted by HSCB> Year to date <number inserted by HSCB>

Question		Comments	Actions
Can both the patient and the pharmacist sit down together?	☐ Yes ☐ No		
Is it possible to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)?	☐ Yes ☐ No		
Is the consultation area clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy?	☐ Yes ☐ No		

Community Pharmacy Assurance Visit Protocol - Part II

Core Essential Service - Dispensing

Service description

The supply of medicines and appliances[1] ordered on HSC prescriptions, together with information and advice, to enable safe and effective use by patients and carers, and maintenance of appropriate records.

Aims and intended outcomes

To ensure patients receive ordered medicines and appliances safely and appropriately by:

- the pharmacy performing appropriate legal, professional, clinical and accuracy checks
- the pharmacy having safe systems of operation
- the pharmacy having systems in place, in line with The Code, to guarantee the integrity of products supplied
- the pharmacy maintaining a record of all medicines and appliances supplied which can be used to assist future patient care
- the pharmacy maintaining a record of advice given, and interventions and referrals made, where the pharmacist judges it to be clinically appropriate

To ensure patients are able to use their medicines and appliances effectively by:

- pharmacy staff providing information and advice to the patient or carer on the safe use of their medicine or appliance
- pharmacy staff providing when appropriate broader advice to the patient on the medicine, for example its possible side effects and significant interactions with other substances

[1] Pharmacies are required to supply any drugs ordered via a prescription. With regards appliances they are only required to supply those that they supply in the normal course of their business.

Q1: Dispensing SOPs

Context
The Responsible Pharmacist Regulations 2008 requires the responsible pharmacist to establish pharmacy procedures designed to ensure the safe and effective running of the pharmacy. These procedures need to be maintained and regularly reviewed:

- 2.5 Pharmacy Procedures are regularly reviewed to ensure they are fit for purpose and reflect the day to day running of the specific pharmacy premises and any changes are documented accordingly

- 2.6 Review of the Pharmacy Procedures occurs every two years as a minimum or at any time that an incident occurs which may potentially have led to a compromise of patient safety

Question	Confirmation/ additional information	Comments	Actions
What SOPs are in place to cover dispensing processes? (an in-depth review will not be undertaken)	If template/company SOPs are used can they be adapted for local use in the pharmacy?		
Are they signed by all relevant staff to say they have read it, understand it, and will follow it, or staff have demonstrated competency and have been signed off by pharmacist?	☐ Yes ☐ No		
Are the SOPs easily accessible by relevant staff? (hard or electronic format)	☐ Yes ☐ No		

Have the SOPs been reviewed within the last two years?	☐ Yes ☐ No		
What is the process for review?			

Q2: Clinical assessment of prescriptions

Context
Pharmaceutical Society of NI Professional Standards & Guidance for the Sale and Supply of Medicines 3.2 &3.4 and HSCB Dispensing Service Specification 2.1, state that a clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient and appropriate records of clinical interventions are made.

Question	Confirmation/ additional information	Comments	Actions
Can you describe the process for undertaking a clinical assessment of a prescription?	Does the process include steps for: • determining the suitability of medication, • appropriateness of the quantity and • dose frequency for the patient?		
Does the pharmacist address clinical queries directly with the prescriber?	☐ Yes where possible ☐ No Do you have any difficulties speaking directly to the prescriber?		
Are interventions and referrals recorded in a log book or PMR?	☐ Yes ☐ No Ask to see an anonymised example. e.g. Is there a record of: • the date and time • patient details • a summary of the query and outcome		

	• the name of the pharmacist and GP/healthcare professional involved?		

Guidance Notes

Clinical Check

Advice on clinical assessment is available in the HSCB Medicines Safety Matters newsletter
http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-community-pharmacists/

In summary the clinical check consists of reviewing:

- **The patient** - characteristics e.g. children or elderly, co-morbidities, patient preferences, allergies
- **The medicines** - indication, dose, frequency, strength, quantity & prescribing interval, interactions, route of administration

Pharmacy Forum has produced Clinical check Guidance which is available at http://forum.psni.org.uk/whats-happening/guidance/

Clinical Queries
Every effort should be made to speak directly to the prescriber if there is a clinical query. This is particularly important where there are serious concerns about patient safety e.g. relating to abuse/misuse, serious drug interactions or overdose. A number of adverse incidents have been reported to HSCB where queries were not discussed between healthcare professionals and guidance on community pharmacy communication with GPs was issued in May 2013 and again in July 2015.
http://www.medicinesgovernance.hscni.net/primary-care/medicines-safety-advice-letters/

Recording Interventions
Records of interventions can be recorded on the PMR or in a designated book. Ideally including:

- the date and time
- a summary of the query and outcome
- patient details
- the name of the pharmacist and GP/healthcare professional involved

Q3: Accuracy of dispensing

Context

Pharmaceutical Society of NI Professional Standards for the Sale and Supply of Medicines:

3 states that patients are entitled to expect the dispensing service provided to be accurate

3.14 requires procedures to be in place to minimise the risk of dispensing errors

Question	Confirmation/ additional information	Comments	Actions
Can you describe the process for undertaking an accuracy check of a prescription			
Is there is a double check built into your dispensing process where possible?	☐ Yes ☐ No		

Guidance Notes

The Royal Pharmaceutical Society of Great Britain suggests the mnemonic HELP maybe be useful when carrying out the final accuracy check on a dispensed medicine:

H – How much has been dispensed
E – Expiry date check
L – Label checks for the correct patient's name, drug name, dose and warnings
P – Product check, i.e. correct medicine, strength and formulation have been supplied

For all prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS, ensure that there is a double check built into your dispensing process where possible. This may be another pharmacist or member of dispensary staff and should be included in your SOP.

Q4: Provision of PILs

Context
Pharmaceutical Society of NI Professional Standards and Guidance for the Sale and Supply of Medicines 3.15 states that a patient information leaflet (PIL) is issued with a medicine at the time of dispensing.

Question	Confirmation/ additional information	Comments	Actions
Do you routinely issue a patient information leaflet (PIL) with each full and part pack of medicine at the time of dispensing? Can you describe the process?	☐ Yes ☐ No What is the process for getting extra supplies of PILs and ensuring they are the most up-to-date editions? Discuss arrangements for supplying PILs with MDS.		

Guidance Notes
Extra copies of leaflets should be available for supply with split packs or stock pots. These could be provided by the manufacturer or by downloading a leaflet.

EMC website: https://www.medicines.org.uk/emc/
MHRA website: http://www.mhra.gov.uk/spc-pil/

Advice on the supply of PILs is given by the Medicines Regulatory Inspectors in their newsletter Issue 3, November 2007 and in respect of MDS in Issue 6, December 2010. https://www.health-ni.gov.uk/publications/pharmacy-inspector-newsletters-june-2006-june-2015

5: Labelling

Context
Pharmaceutical Society of NI, Professional Standards and Guidance for the Sale and Supply of Medicines 3.11, states that labelling of dispensed products is clear and legible, computer-generated and where appropriate includes any cautionary and advisory labelling recommended by the BNF.

Question	Confirmation/ additional information	Comments	Agreed Actions
Do you ensure a label is supplied with each pack/container*?	☐ Yes ☐ No Does MDS packaging contain a label for every item supplied in the compliance aid?		

Guidance Notes

Medicines Regulatory Group Inspectors Newsletter No 10 March 2015 includes a message from the Pharmaceutical Society of NI Registrar on managing labelling risks. “Good professional practice requires each and every product should be supplied with its own discrete label to aid patients and carers in ensuring the safe and correct usage of the product “. https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/pas-pharmacy-newsletter-10.pdf

* Possible exceptions to this may be the supply of dietetic products or surgical products where outer packaging could be labelled once. Consider labelling for all types of prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS.

Q6: Provision of advice to patients

Context
Pharmaceutical Society of NI Professional Standards and Guidance for the Sale and Supply of Medicines:

- 3.3 requires that the patient receives sufficient information and advice to enable the safe and effective use of the prescribed medicine and
- 6.3 that the pharmacist must ensure that the delivery mechanism used enables the medicine to be delivered securely and promptly to the intended recipient with any necessary information to enable safe and effective use of his medicine

HSCB Dispensing Service Specification 3.3 requires that appropriate advice is given to the patient to enable them to utilise the medication or appliance and to meet their personal need for general information on the item.

Question	Confirmation/ additional information	Comments	Actions
Do you ensure that appropriate advice is given to patients (or their representatives) on their prescribed medicines including home deliveries, for • New medicines • Changes to medicine dose or formulation • High risk medicines	☐ Yes ☐ No What steps are taken to ensure that advice is given when a prescription is handed out in the pharmacy e.g. use of alert labels etc.? What steps are taken to ensure that advice is given when a prescription is delivered?		

Guidance Notes
HSCB High Risk Medicines Poster (CP version) is available at: http://www.medicinesgovernance.hscni.net/primary-care/posters-leaflets/

Q7: Safe storage of medicines

Context
HSCB Dispensing Service Specification 3.4 requires that patients are advised on the safe storage and keeping of medicines and of the recommendation that unwanted medicines should be returned to the pharmacy for safe destruction.

Pharmaceutical Society of NI Standards for Sale and Supply of Medicines 3.10: The pharmacist must ensure that all solid dose and all oral and external liquid preparations are dispensed in suitable re-closable child resistant containers unless:

- The medicine is in an original pack or patient pack such as to make this inadvisable;
- The patient has difficulty in opening a child resistant container;
- A specific request is made by the patient, their carer or representative that the product is not dispensed in a child resistant container;
- No suitable child resistant container exists for a particular liquid preparation; or
- The patient has been assessed as requiring a compliance aid.

Pharmaceutical Society of NI Standards for Sale and Supply of Medicines 1.7: The pharmacist must ensure that the removal of medicines from blister or foil packs only, where required, at the time of dispensing, is to assist an individual patient. In doing so, the integrity of the medicine must not be impaired.

Question	Confirmation/ additional information	Comments	Actions
How do you ensure patients are advised on the safe storage and keeping of medicines?	Discuss the process e.g. practice leaflet		
How do you raise awareness with patients that unwanted medicines should be returned to the pharmacy for safe destruction?	e.g. DUMP campaign, practice leaflet		

How do you check the suitability of medicines that are supplied in MDS?	e.g. UKMI Medicines Compliance Aid Database		

Guidance Notes

Consider advice on safe storage e.g. for fridge lines and methadone, and other medicines with special advice for disposal e.g. eye drops requiring disposal after 28 days, safe disposal of patches.

Consider advice on the disposal of unwanted medicines either verbally or written as appropriate e.g. note on dispensing bag or posters/leaflets.

Medicines Safety Matters Community Pharmacy Vol 3 Issue 2 (July 2015) focused on incidents involving Monitored Dosage Systems, how to reduce the associated risks and advice on drug stability.
Information on the stability of medicines prior to dispensing in MDS can be accessed on the Specialist Pharmacist Service Website https://www.sps.nhs.uk/?s=&cat%5B%5D=266&cat%5B%5D=3253. Enter the drug name in the search bar, click on the specific medicine that is retrieved on the list that is displayed, and scroll down the page to the advice on MCA stability for that specific medicine.

Q8: Checking patient details

Context
Pharmaceutical Society of NI Standards and Guidance for the Sale and Supply of Medicines 3.14, requires that procedures are in place to minimise the risk of dispensing errors.

Question	Confirmation/ additional information	Comments	Actions
Can you describe the process for confirming patient details, before handing out medicines, to ensure the right patient gets the right prescription • In your pharmacy? • When medicines are delivered?	Are you aware of the "Right Person" poster?		

Guidance Notes

E.g. Pharmacy staff say the patient's name and ask the patient/carer for the address.
Consider all types of prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS.

HSCB "Right Person" poster is available at**:** http://www.medicinesgovernance.hscni.net/primary-care/posters-leaflets/

Q9: Patient Safety

Context
Pharmaceutical Society of NI Code for Professional Standards of Conduct, Ethics and Performance, Principle 2 requires pharmacists to provide a safe and quality service with Standard 2.2. focusing on Managing Risk. These require pharmacists to:

2.2.1, Undertake a regular risk assessment in relation to your professional practice and the procedures that you follow
2.2.2, Apprise staff of medication safety issues, identify areas of high-risk practice and implement procedures and processes to minimise medication safety risks or associated issues arising
2.2.3, Where any risk, issue or problem is identified, arises, or occurs in your practice, take prompt action to prevent, minimise, follow up and resolve any such risk, issue or problem, and this includes risks, issues or problems relating to medicines and appliances.
2.2.4, Keep abreast of medication safety alerts and other publications to ensure the safety and quality of pharmacy services
2.2.5, Contribute appropriately to “near-miss” and error reporting systems.

Pharmaceutical Society of NI Professional Standards for the Sale and Supply of Medicines 3.14 requires procedures to be in place to minimise the risk of dispensing errors or contamination of medicines and a record of errors and near-miss incidents must be made and practices reviewed in light of such incidents.

Question	Confirmation/ additional information	Comments	Actions
What is the process for disseminating patient safety communications e.g. HSC Learning Letters, Medicines Safety Matters Newsletters and other relevant communications from the HSCB to dispensing staff?*			
How do you record medicines incidents and near-misses?	Ask to see an anonymised example of an incident or near miss record.		

How do you review practice with relevant staff in light of any incidents e.g. in the pharmacy or one highlighted in a patient safety communication?			

Guidance Notes

* Medicines safety advice, letters and newsletters are available on the NI Medicines Governance Website http://www.medicinesgovernance.hscni.net/primary-care/

Q10a Topic of current interest – Beta blockers

Additional Context
Communications have been issued by HSCB to share learning from a number of adverse incidents where beta blockers were involved in selection errors at the point of dispensing, some of which had serious consequences for the patients involved. Confirmation was required from pharmacies that the actions from the Beta blocker learning letter issued in May 2014 were completed.

Question	Confirmation/ additional information	Comments	Actions
HSCB has a record of pharmacy confirmation that the actions from the Beta blocker learning letter were completed? < completed by HSCB>	☐ Yes ☐ No		
Were the following communications and their recommendations shared with and discussed by relevant staff? • MSM newsletter with information on risks about incorrect selection of beta blockers (August 2013)? • Beta blocker learning letter (May 2014)? • Further dispensing errors involving beta blockers letter (July 2015)? • Learning from Serious Adverse Incident (February 2017)	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No		

Did you make any changes or consider changes to practice as a result of the letter i.e. • Changes to the storage of beta blockers (separate area or/shelf edging), • Added an alert to the computer to highlight drugs which have the potential to be mis-selected, • Consideration of packaging in procuring generic medicines?	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No		
Have you identified any further learning points which could be shared with others e.g. following an incident involving beta blockers in the pharmacy or as a result of discussing the recommendations in HSCB communications?	☐ Yes ☐ No		

Guidance Notes

Medicines Safety Matters Newsletter (August 2013)

http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-community-pharmacists/

HSCB/PHA Safety and Quality Learning Letter: Dispensing Beta Blockers – Selection Errors (May 2014) <Copy enclosed by HSCB>

HSCB Urgent communication: Further Dispensing Errors involving Beta blockers (July 2015) <Copy enclosed by HSCB>

HSCB Learning from Serious Adverse Incident (February 2017) http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-community-pharmacists/

Pharmacy Representative/s present:

Name **Job Title**

HSCB Representative/s present:

Name **Job Title**

Date

Email included on the Assurance Declaration _____

Report to be sent by email/post (delete as appropriate) to:_____

References

The Terms of Service are set out in http://www.legislation.gov.uk/nisr/1997/381/contents/made

Pharmaceutical Society of NI Standards http://www.psni.org.uk/about/code-of-ethics-and-standards/

HSC Dispensing Service Specification http://www.hscbusiness.hscni.net/services/2652.htm