

Canice Ward
Medicines Regulatory Group

BY EMAIL

Trust Heads of Pharmacy & Medicines Management
HSCB – Asst Director, Head of Pharmacy & Medicines Mgt
(for onward distribution to Registered Pharmacies)
Registrar Pharmaceutical Society NI
Chief Executive CPNI
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Date: 20 February 2019

Dear Colleague,

RE: DECLARATIONS AND SELF-ASSESSMENTS

This letter is for the attention of and action by all registered pharmacies in relation to the **2019 Declarations and Self-assessments form** which arises from The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 and should be completed no later than **31 March 2019**. Non-registered Trust pharmacies should also complete the form in anticipation of the next controlled drugs inspection. Further information about these Regulations can be found on the Department's web-site at <https://www.health-ni.gov.uk/articles/accountable-officer>

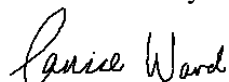
The arrangements for declarations and self-assessments are as follows:-

For all community pharmacies and HSC Trust pharmacies, a declaration and self-assessment form in relation to the management of controlled drugs must be completed annually. The completed form is to be retained in the front of the Controlled Drug register and will become part of the routine record-keeping which will be examined by the Pharmacy Inspectors during their visits.

A copy of the declaration and self-assessment is enclosed for completion in readiness for your next pharmacy inspection visit. A copy of this form can also be found on the Department of Health's website at the following link:
<https://www.health-ni.gov.uk/articles/letters-and-advice-regulation-medicines>

If you have any queries, regarding the completion of this form, please contact Fiona Taylor (02890 528688) fiona.taylor@health-ni.gov.uk or Canice Ward (02890 523703) canice.ward@health-ni.gov.uk

Yours sincerely



Medicines Regulatory Group , Department of Health

DECLARATION AND SELF ASSESSMENT 2019
ALL QUESTIONS MUST BE ANSWERED

	Yes/No		Yes/No
1. Do you have specific written SOPs covering the management of CDs, appropriate to the activities carried out at the premises and as required by the Accountable Officer regulations?		7. Do you transport CDs in accordance with an SOP (e.g. patient deliveries)?	
2. Are the staff involved in activities related to CDs appropriately trained and competent?		8. Are all CDs appropriately labelled?	
3. Do you have procedures in place to identify, deal with and learn from significant incidents involving CDs?		9. Are regular date checks of CD stock carried out?	
4a. Have you noted any signs of unusual, excessive or inappropriate supply or prescribing patterns?		10. Is the CD Register maintained in accordance with the Misuse of Drugs Regulations and any relevant guidance?	
4b. If yes , have these issues been fully addressed?		11. Are running balances of CDs maintained in the CD register and is there evidence that they are audited?	
5a. Are there any signs of, or do you have concerns about, the diversion of CDs?		12. Are all relevant CDs stored in accordance with the Safe Custody Regulations and are procedures in place to prevent unauthorised access to CDs?	
5b. If yes , have these issues been fully addressed?		13. Is date expired and patient returned medication appropriately marked and segregated?	
6a. Have there been any complaints or significant incidents involving CDs in the last 12 months of which you are aware?		14. Are out of date or patient returned CDs (S 2, 3, 4 and 5 CDs) denatured in line with published guidance, prior to pharmaceutical waste disposal?	
6b. If yes , have these issues been fully addressed?		15. Are prescriptions for Schedule 2 & 3 CDs endorsed with the date of supply at the time of supply?	

DECLARATION

I declare that to the best of my knowledge and belief that the handling, management and use of controlled drugs, in all Schedules, at these premises complies with the provisions of the Misuse of Drugs Act 1971, its associated regulations and the Health Act 2006 and its associated controlled drugs regulations.

Signed

Date

Name		Registration Number	
Position within organisation		Name of organisation and address of premises	