ANNEX B - Consultation Reply Form

Draft Regulations: The Controlled Drugs (Supervision of Management and Use) Regulations 2013

Consultation Reply Form

1. This consultation starts on 27 September 2012. Responses should be sent using the consultation reply form below no later than noon 15 November 2012 to: robert.allan@dh.gsi.gov.uk. Alternatively, copies can be sent by post to:

   Robert Allan
   Department of Health,
   Medicines Pharmacy and Industry Group,
   Room 5W25,
   Quarry House,
   Leeds LS2 7UE

2. A list of organisations to which this consultation has been sent is attached at Annex A.

Please fill in the appropriate response.

Response form

The draft Controlled Drugs (Supervision of Management and Use) Regulations 2013 and supporting documents.

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Organisation representing (if appropriate): Royal Pharmaceutical Society

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Contact email:heidi.wright@rpharms.com

General comments:

The changes suggested in this consultation have come about due to the reforms in the NHS. Whilst we don't think the changes proposed in this consultation will have much of an impact on daily practice for those working in either community or hospital pharmacies it will impact on primary care pharmacists, many of whom currently undertake the role of Controlled Drugs Accountable Officer (CDAO). NHS Trusts and community pharmacies will need to consider where they sit as an organisation within the Local Intelligence Networks (LINs). The key to good CD management remains the local intelligence network and the 'duty to share'.

There are a number of issues in relation to CDs that need to be considered outside of this consultation, some of which we raised in our response to the 'Red Tape Challenge'

In general, we believe that the role of the CDAO has focused too much on the systems and processes and has not really made an impact on the number of adverse events experienced by patients in relation to CDs. There should be a change in focus to look at patient outcomes.

In the consultation document the LIN appears to have moved from a local intelligence network to a local involvement network. We believe that the difference between the two is important as the LINs are all about sharing information so it is about building intelligence rather than simply passive involvement. We assume this is just a drafting error.

Questions for Part 1 - Interpretation

Q1 Do you agree that small businesses with fewer than 11 employees should be exempt from the requirements to appoint a CDAO in England and Scotland?

Comment:

The key is not the size of the business, but whether or not the use of CDs is a 'critical' component of the business. We believe that there needs to be a better test. A potential solution is for businesses who consider that this legislation is not of significance to them to 'apply' for exemption through CQC.

If however, the employee count was to remain as a guide then it should not just include volunteers but also contractors, for example in the private sector the vast majority of clinician input is through 'contractor' relationships and not direct employment.

Q2 Do you agree that English and Scottish regulators (CQC and HIS) should be

able to determine, where it is desirable for them to do so, that smaller organisations with more than 11 staff should not be required to appoint a CDAO and the proposed criteria that the CQC and HIS would adopt? If not, please explain your reasons.

Comment:
No, please see our response to Q1. The main factor is whether or not the use of CDs is a critical component of the business.

Q3 *Do you agree the list of "responsible bodies" that will be members of LINs for England or Scotland?*

Comment:
The legislation seems to suggest NHSBA needs to attend every LINs which we feel would not be feasible.

Q4 *For England, do you agree that CCGs and LAs should not be required to appoint a CDAO?*

Comment:
The rationale behind this is that both CCGs and LAs are commissioning bodies, however so are PCTs who do have to appoint a CDAO. PCTs also had to take the lead in the local LIN area. This has resulted in a lot of good work amongst local organisations sharing intelligence, processes, documents etc. Valuable relationships and trust have been established, especially with agencies out with the NHS – most notably the police. It would be detrimental to lose these networks during the reforms. The concern about the CDAO role sitting at NHSCB level is that individual practitioners will be too remote from the CDAO and the local communities that they serve, as there will only be 27 LATs across England. AS CCGs will be responsible for the governance of their organisations they need to consider how they deal with CDs and the 'duty to share'.

Q5 *Do you agree the list of "designated bodies" required to appoint CDAOs, including the armed forces? For England, this would mean that the NHS Commissioning Board will be required to appoint CDAO(s) under the criteria set out in Part 2 below.*

Comment:
We seek clarity as to what is meant by 'co-operate' in para 11 i.e. "CCGs and LAs in England will be obliged to ***co-operate*** with the NHSCB's lead CDAO". This term is vague and if CCGs and LAs are not mandated as to what they are expected to co operate on then this could lead to disengagement. We are also concerned that the number of CDAOs and therefore LINs will be a lot less if there will only be one per

NHSCB local area teams. We are concerned that if CCGs are not required to have a CDAO there is a risk that the organisation may not feel it has a statutory responsibility to ensure CD governance within its organisation.

Our main concern is that there will not be the enough pharmacist expertise within the NHSCB with the necessary skills, knowledge and authority to undertake the CDAO role and the necessary competence to manage and interpret relevant data.

We also feel that Social Enterprise bodies registered as a community provider of health care through the DH Transforming Community Services should also be included. Hospices tend to be heavy users of CDs and should therefore also be included.

Questions for Part 2 – Accountable Officers

Q6 *Do you agree the requirements for, and the simplified list of functions of, CDAOs set out in Part 2? If not, please indicate why.*

Comment:
No, it needs to be explicitly laid out what authority the CDAO has. This is particularly important if needing to undertake visits and investigations about individual practices and pharmacies. It is vital that local intelligence is taken on board before action is taken.

In particular paragraph 8(2) and 8 (7)(b) are very difficult to understand. The definition of senior manager is too loose and we believe that the previous definition of reporting to a Director was better.

Para 11 does not seem to mention overseeing safe destruction of CDs which is an important role for CDAOs and we believe should be specified.

Para 13 (4) is confusing. The responsibility for pharmaceutical remuneration will be the NHSCB via the contract, not the CCG.

Q7 *Do you agree that the draft Regulations should not specify the precise requirements for Standard Operating Procedures but leave this to the CDAO's judgement?*

Comment:
No, we believe that this needs to be kept as mandatory so that there are standards to specifically monitor against.

In paragraph 15 "CDAOs must ensure **relevant people** receive information, education or training on CD SOPs". This is too loose and open to interpretation as to who the 'relevant people' are so they should be specified.

Q8 *In England, do you agree that CCGs must be under a regulatory duty to co-operate with the NHS CB CDAO over monitoring of their prescribers, or is there a better way of securing this co-operation?*

Comment:
Yes but "co-operation" needs to be defined as does the authority, accountability and powers of the CDAO. CCGs will need to be mandated to ensure that there are sufficient resources in place for this to be undertaken. Any monitoring needs to be explicit as to what this means in terms of information gathering and actions needed. We think the expectation should be that the NHSCB is expected to provide resources if required.

Questions for Part 3 – Responsible bodies

Q9 *Do you agree that, in England, the responsibility for setting up Local Involvement Networks (LINs) should sit with the NHS Commissioning Board? If not, please explain why and with whom this responsibility should sit.*

Comment:
As above we think that the NHSCB LATs are too large an area for LINs. This would have to be done in conjunction with the people who have been running LINs in the area up until now to understand the issues for the area. The NHSCB may be able to advise, at a local level, what the optimal size of a LIN should be in there particular locality.

Q10 *If you do agree this responsibility should sit with the NHS Commissioning Board, do you also agree it should determine how many LIN areas it establishes for which it will appoint the CDAO? If not, please explain why and what alternative you would prefer.*

Comment:
As above we think that NHSCB local teams span too large an area for a workable LIN and should build on the areas which are working well at the moment. Perhaps the NHSCB LAT could provide an umbrella role for a number of LINs in their area.

Q11 *Do you agree that local lead CDAOs should have discretion over the membership of LINs?*

Comment:
No, this needs to be laid down in regulations otherwise the relevant people may not prioritise this work and relevant members may be overlooked.

Q12 *Do you agree the proposals for sharing information between responsible bodies?*

Comment:
Yes, memoranda of understanding have been put in place and these should be built

on. This is particularly important regarding information sharing between the NHS and police.

Q13 *Do you agree that local lead CDAOs should be able to share information about individuals where there are concerns about that person's controlled drugs activities with employer organisations irrespective of whether those organisations are members of the LIN or not? (It is proposed to provide further information on the operation of this provision in the guidance to be prepared to accompany the final Regulations once approved).*

Comment:
Yes. Para 14(4) seems to omit Dentists and we are not sure if this is correct as we believe that Dentists should also be required to complete self-assessments. Para 14 should be clear that CCG prescribing leads should be part of the LIN membership
Para 15 (2) should be MUST not MAY share information as there should be clear unambiguous expectation to share this information.

Questions for Part 4 – Inspection and supplementary matters

Q14 *Do you agree the provisions set out here concerning inspections and required reporting?*

Comment:
It needs to be made clear if this only applies to NHS premises or to private premises too.

Q15 *Are there any areas omitted that you think should be included?*

Comment:
No

Q16 *Are there alternative enforcement options or existing powers of entry that could be used instead of the measures set out here?*

Comment:
No

Questions for other aspects of the proposed 2013 Regulations

Comment:
There is no legislative requirement for CDAOs to be able to request wholesaler information on the supply of CDs to Dispensing Doctors, Dentists and others. We believe that this is a deficiency in the legislation and this loophole should be closed.

Q17 *Do you agree these "better regulation" measures? If not, please explain why if you have not done so earlier in your reply.*

Comment:
Their needs to be clarity around the authority, responsibility and accountability of inspectors to ensure co-operation by providers. There is no reference to Providers of Community Services premises e.g. Community Hospitals, District Nurse bases etc.

Q18 Are there other measures not included here which you believe would improve the way these Regulations work?

Comment:
The role of the CQC and LINs needs to be explicit as they do not appear to have a duty to share information regarding concerns about Care Home staff.

Questions about the consultation impact assessment

Comment:

Q19 Do you agree with the assumptions and methodologies used to assess the costs and benefits in the Impact Assessment? For example, we are assuming that 5% of potential adverse patient incidents involving controlled drugs will be avoided under this new regulatory regime, as compared against the do-nothing option. Is this a reasonable representation of prevented patient harm?

Comment:
We are unclear as to where this figure of 5% has been derived and would be keen to understand what evidence has been used in the calculation.

We are concerned that there could be an increase in adverse incidents as the current local working and relationships could get lost.

Q20 Are there other factors, costs or benefits which the Impact Assessment should take into account which are not set out here?

Comment:
It is vitally important that historic knowledge is taken into account so that organisational memory is not lost.

Q21 Do you have any other comments on the Impact Assessment?

Comment:
No

Questions about the Equality Statement

Q22 Do you agree the Department's analysis set out in the Equality Statement?

Comment:
Yes

Q23 *Are you aware of any adverse impacts these Regulations have had on the timely prescribing and administration of controlled drugs for patients, or on different groups of people? The Department welcomes your comments and views as to whether we have missed any issues affecting different groups of people as set out in the accompanying document.*

Comment: No

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter.**

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

I do not wish my response to be published in a summary of responses ☐

Are you responding:

- on behalf of an organisation ☐

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

Area of work:

NHS	
Third Sector	
Regulatory Body (GPhC etc)	
Professional Body (LPC etc)	X
Education	
Trade Union/Negotiating body	
Pharmacy/appliance provider	
Local Authority	
Trade Body	
Manufacturer	
Supplier	
Other (Please give details)	

live: (please tick *one* box only)	
North East	
North West	
West Midlands	
South East	
London	
Humberside/Yorkshire	
East Midlands	
East of England	
South West	
No answer	X

If you are responding on behalf of an organisation, please indicate which type of organisation you represent:

Patients	
NHS – PCT/SHA	
NHS – GPs, nurses etc.	
Local Pharmaceutical Committee	
Local Medical Committee	
Private Health/Independent Sector	
Third Sector	
Regulatory Body (GPhC etc)	
Professional Body	X
Education	
Trade Union/Negotiating body	
Local Authority	
Trade Body	
Other (Please give details)	

In which of the following areas do you

Organisations do not need to answer questions 1-7

1 What is your sex?
Tick one box only.

Male	
Female	X
Prefer not to say	

2 What is your Age?

Age	41
Prefer not to say	

3 Are your day-to-day activities limited because of any health problem or disability which has lasted, or is expected to last at least 12 months?

Tick one box only.

Yes, limited	
Yes, limited, a little	
No	X
Prefer not to say	

4 Do you look after, or give any help or support to family members, friends, neighbours or others because of either long-term physical or mental ill-health/disability or problems related to old age?
Tick one box only.

Yes	
No	X
Prefer not to say	

5 What is your ethnic group?
Tick one box only.

A White

British	X
Irish	

Any other White background, write below

B Mixed

White and Black Caribbean	
White and Black African	
White and Asian	

Any other Mixed background, write below.

C Asian, or Asian British

Indian	
Pakistani	
Bangladeshi	

Any other Asian background, write below

D Black, or Black British

Caribbean	
African	

Any other Black background, write below

E Chinese, or other ethnic group

Chinese	

Any other, write below

F Prefer not to say

6 What is your religion or belief?
Tick one box only.

Christian includes Church of England, Roman Catholic and all other Christian denominations.

None	
Christian	X
Buddhist	
Hindu	
Jewish	
Muslim	
Sikh	
Prefer not to say	
Other, write below	

7 Which of the following best describes your sexual orientation?
Tick one box only.

Only answer this question if you are aged **16** years or over.

Heterosexual Straight	X
Lesbian / Gay Woman	
Gay Man	
Bisexual	
Prefer not to say	
Other, write below	