Controlled Drugs (Supervision and Management of Use) Regulations 2013 - Questionnaire

The Department of Health and Social Care, working with the Scottish Government, are committed to reviewing the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (the "2013 Regulations") by 30 March 2025. In England, this is part of the Department's commitment to reviewing certain regulations post implementation according to the duty to review secondary legislation provisions arising from the Small Business, Enterprise and Employment Act 2015.

Following the completion of the last review in 2018 The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (legislation.gov.uk), the Department updated the regulations (The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020), subsequently removed the 'sunset clause', and updated definitions to reflect the healthcare system in England and Scotland. Sunset clauses are an expiry date included in legislation when it is felt that Parliament should have the opportunity to decide on the legislation's merits again after a fixed period. Removal of the sunset clause resulted in the maintenance of this important legislation.

Post-implementation evaluation is critical in ensuring that these regulatory interventions are delivering the intended outcomes, in identifying any unintended consequences and in re-evaluating estimates of the costs and benefits, to ensure these accurately reflect the impacts to business and society. Reviewing regulations also enables us to learn lessons from previous interventions and apply these in the future.

The primary purpose of this review is to reflect on the original policy objectives - - the extent to which the Regulations continue to achieve their intended effects and whether there have been any unintended consequences, and the reasons why. It will also assess whether the objectives could be better achieved via other means - for example through guidance. This questionnaire aims to assist policy makers in answering these questions and gathering evidence and data to inform the review of the Regulations.

The purpose of this questionnaire is to inform our review of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (as amended) and the framework underpinning the governance and accountability of controlled drugs in England and Scotland.

Wider matters regarding controlled drugs and the misuse of drugs are not being considered as part of this review.

This questionnaire will be open from 01/09 and 30/09. Please use the navigation buttons below to proceed through the questionnaire, and ensure you press Submit on the final page.

Your input and views are appreciated.

Overview of the 2013 Regulations

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 apply to England and Scotland and perform a key role in the strengthening of controlled drugs governance arrangements. The regulations were introduced in response to the findings of the Shipman and Gosport inquiries which investigated system failures concerning the serious mismanagement of controlled drugs. The 2013 Regulations are split into a three-part framework:

Firstly, the 2013 Regulations appoint particular bodies as "designated bodies". These include NHS trusts, NHS foundation trusts, Health Boards, English and Scottish independent hospitals, NHS England and regular or reserve forces headquarters. Designated bodies are required to appoint or nominate a Controlled Drugs Accountable Officer (CDAO). Each CDAO is responsible for securing the safe management and use of controlled drugs (CDs) within their organisation, and each must ensure appropriate systems are in place for the use, monitoring, recording and auditing of CDs. CDAO's must therefore be a fit, proper and suitably experienced person. This is commonly accepted to be a senior employee (or a direct report to a board member) so that they have the seniority and autonomy to investigate any CD incident. The 2013 Regulations require CDAOs to establish and operate any monitoring and assessment requirements as regards persons relevant to CD incidents, where necessary. They also necessitate CDAOs to consider, investigate and take appropriate action in response to incidents relating to the safe management and use of CDs. Designated bodies that have an CDAO must ensure funds and other resources necessary for enabling the CDAO to discharge their responsibilities as accountable officer are made available.

Secondly, the 2013 Regulations provide for the establishment of "Local Intelligence Networks" (LINs), and NHS England in England and the Health Boards in Scotland are tasked by the 2013 Regulations with appointing or nominating "local lead" CDAOs in respect of the management of these LINs. The purpose of LINs is to facilitate the co-operation of designated bodies and "responsible bodies" (including designated bodies such as commissioners and providers of health care, but also enforcement and regulatory agencies such as the CQC, Healthcare Improvement Scotland (HIS) and the police), as concerns the identification, consideration of issues and taking of action relating to CD incidents occurring in that LIN's locality. The LINs must cover the entire geography of England and Scotland - covering the 7 Scottish Health Boards in Scotland and the 7 Regions of NHS England in England. Local lead CDAOs are also afforded powers to request periodic declarations and self-assessments in relation to the safe use and management of CDs from organisations directly handling/utilising them (provider bodies).

Thirdly, the 2013 Regulations cover ancillary matters such as carrying out inspections, and enable the Care Quality Commission, Healthcare Improvement Scotland, the General Pharmaceutical Council and the Care Inspectorate to obtain information about how CDs are being used and managed in regard to relevant organisations.

Overview of 2013 regulations - continued.

The overarching objectives of the 2013 Regulations are to:

· Maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs;

· Protect patient and public health;
· Promote co-operation and information sharing between different local bodies and organisations;
· Enable effective mechanisms to monitor and audit the use of controlled drugs; and
· Enable adequate powers to investigate, and take prompt and effective action where appropriate, when concerns are raised.

The purpose of this review is to assess how each of these five broad areas has been functioning in every day practice, and assess any opportunity for improvement.

An electronic version of the 2013 Regulations can be found here: The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (legislation.gov.uk)

General Information

1. What is your name *

   Fiona McIntyre

2. What is your email address? *

   fiona.mcintyre@rpharms.com

3. What is your job title *

   Policy & Practice Lead, RPS Scotland

4. In what context are you responding to this questionnaire? *

- ○ As a member of the public
- ○ As a "local lead" Controlled Drugs Accountable Officer (or a member of a “local lead”
- ○ Controlled Drugs Accountable Officer’s team
- ○ As a Controlled Drugs Accountable Officer
- ○ As a health and social care professional
- ◉ On behalf of an organisation

- ( ) NHSE CDAO
- ( ) Scotland CDAO
- ( ) Controlled drugs Liaison Officer
- ( ) Other

5. If you are responding on behalf of an organisation, what is that organisation's name? *

Royal Pharmaceutical Society

6. Do you work in the NHS or in a private healthcare service *

- (•) NHS
- ( ) Private healthcare services

7. Which of the following best describes where you work? *

- [ ] Ambulance Service
- [ ] Care Home
- [ ] Clinic (e.g. In Vitro Fertilisation (IVF), Cosmetic Surgery, Eye Surgery, Weight Loss, Hair Transplant)
- [ ] Community Pharmacy
- [ ] Police Force or similar
- [ ] Dental Practice
- [ ] General Practice
- [ ] Independent Hospital (including Independent Hospital Pharmacy)

- [ ] NHS Hospital (including Hospital Pharmacy)
- [ ] NHS England
- [ ] Prison Healthcare (including detention centres and custody suites)
- [x] Professional/Representative Body
- [ ] Regular or reserve forces
- [ ] Regulatory Body
- [ ] Scottish Health Board
- [ ] Scottish Special Health Board
- [ ] Substance Misuse Organisation (not in a prison)
- [ ] Integrated Care Board (ICB)
- [ ] Other

8. If you stated other, please specify.

Please enter at most 150 characters

9. How many employees are there in your organisation? (Please include all branches and subsidiaries) *

- ( ) Between 1 and 9
- ( ) Between 10 and 49
- ( ) Between 50 and 249
- ( ) More than 250
- (•) Not applicable

- ( ) I don't know

10. Who is the primary regulator of your organisation? *

- ( ) Care Quality Commission (CQC)
- ( ) Care Inspectorate
- ( ) General Pharmaceutical Council (GPhC)
- ( ) Healthcare Improvement Scotland (HIS)
- ( ) Home Office (HO)
- ( ) Medicines and Healthcare products Regulatory Agency (MHRA)
- ( ) Royal College of Veterinary Surgeons (RCVS)
- ( ) Human Fertilisation and Embryology Authority (HEFA)
- (•) Not applicable
- ( ) I don't know
- ( ) Other

11. Which country do you work in? *

- ( ) England
- ( ) Scotland
- (•) Across Great Britain

12. If you work in England, which NHS England Region do you work in? [NHS England Regions]

- ( ) North East and Yorkshire
- ( ) North West
- ( ) Midlands
- ( ) East of England
- ( ) South West
- ( ) South East
- ( ) London
- ( ) I don't know

13. If you work in Scotland, which area do you work in?

- ( ) Dumfries and Galloway
- ( ) Borders
- ( ) Ayrshire and Arran
- ( ) Greater Glasgow and Clyde
- ( ) Lanarkshire
- ( ) Forth Valley
- ( ) Lothian
- ( ) Fife
- ( ) Tayside
- ( ) Highland
- ( ) Grampian

- ( ) Orkney
- ( ) Shetlands
- ( ) Western Isles
- ( ) I don't know

Controlled Drugs

14. Does your organisation interact with (e.g. hold/supply/manage) controlled drugs? *

- ( ) Yes
- ( ) No
- (•) I don't know

15. Are you a Controlled Drugs Accountable Officer? *

- ( ) Yes
- (•) No

16. Do you work in an English or Scottish independent hospital that is exempt from the Regulations, either due to having fewer than 10 individuals working at the hospital or through a determination of exemption from the Care Quality Commission or Healthcare Improvement Scotland? *

- ( ) Yes
- (•) No
- ( ) I don't know

Definitions and Governance

The 2013 Regulations define multiple phrases used throughout the Regulatory document. This includes the meaning of "English independent hospital", "Scottish independent hospital", "relevant persons", "responsible bodies" and "designated bodies".

English and Scottish Independent Hospitals

A body is determined to be an English or Scottish independent hospital if it runs a hospital in England/Scotland at or from which health care is provided to individuals and which is not a "health service hospital" within the meaning of the Health Act 2006 - unless, fewer than 10 individuals work at the hospital or the body has requested, and been granted, a determination from the Care Quality Commission / Healthcare Improvement Scotland that requiring the body to nominate or appoint a Controlled Drugs Accountable Officer would give rise to disproportionate difficulties.

Designated Bodies

A body is determined to be a "designated body" if, in England, it is regarded as: an NHS Foundation Trust; an NHS Trust; an English independent hospital; the NHS Commissioning Board (i.e. NHS England); or the HQ in England of regular or reserve forces.

A body is determined to be a "designated body" if, in Scotland, it is regarded as: a Health Board; a Scottish independent hospital; the HQ in Scotland of regular or reserve forces; or one of the following Special Health Boards - the Scottish Ambulance Service Board; the National Waiting Times Centre Board; the headquarters of the regular and reserve forces and the State Hospitals Board for Scotland.

Relevant Persons

An individual is determined to be a "relevant person" if they are a health care professional who provides health care services to patients on behalf of a local authority providing health services, or to private patients outside of an independent hospital, where doing so does or may involve activities relevant to the safe management and use of controlled drugs. Furthermore, the determination applies to care home managers and people assisting them, and where an individual, not being a health care professional, is engaged with relevant activities carried on with or on behalf of a health care professional.

Responsible Bodies

A body is determined to be a "responsible body" if, in England and Scotland, it is regarded as: a regulatory body; a local authority; a police force; a designated body; or a country-specific body, as named in the Regulations - in England – an Integrated Care Board (ICB)), NHS Protect, Prescription Pricing Division of the NHSBSA or the Care Quality Commission. In Scotland - the Scottish Counter Fraud Services, Common Services Agency (Information Services Division and Practitioner Services division), Healthcare Improvement Scotland or the Care Inspectorate.

ICBs, were introduced in the Health and Care Act 2022, with one ICB in each Integrated Care System area of England. They are responsible for planning health services for a local population and for managing NHS budgets. ICB's work with local providers of NHS services including hospitals and general practices to deliver the strategy of the local Integrated Care Partnership.

17. Are there any changes/amendments required to the definitions of "English and Scottish independent hospitals" in the 2013 Regulations? *

- ○ Yes
- ○ No
- ◉ No view

18. If you answered Yes, can you please elaborate on what changes you think are required.

    Please enter at most 150 characters

19. Are there any changes/amendments required to the definition of "relevant persons" currently outlined in in the 2013 Regulations *

- ○ Yes
- ○ No
- ◉ No view

20. If you answered Yes, can you please elaborate on what changes you think are required.

    Please enter at most 150 characters

21. Are there any changes/amendments required to the definition of "designated bodies" currently outlined in the 2013 Regulations? Should any bodies be added or removed? *

- ○ Yes
- ○ No
- ◉ No view.

22. If you answered Yes, can you please elaborate on what changes you think are required.

Please enter at most 150 characters

23. Are there any changes/amendments required to the definition of "responsible bodies" currently outlined in the 2013 Regulations? Should any bodies be added or removed? *

- ○ Yes
- ○ No
- ◉ No view

24. If you answered Yes, can you please elaborate on what changes you think are required.

Please enter at most 150 characters

25. **Are there any new models of health care that are not adequately covered by the regulations?** *

- ◉ Yes
- ○ No
- ○ No view

26. If you answered Yes, can you please elaborate what else you think needs to be considered.

Concerns over the increasing number of online controlled drug prescribers and a need to tighten the governance arrangements for these organisations.

27. Is there anything else concerning the new ways of working that we need to be aware of in regard to the 2013 Regulations? *

- (●) Yes
- ( ) No
- ( ) No view

28. If you answered Yes, can you please elaborate what else you think needs to be considered.

A responsible person be identified (e.g. CDAO or CD Responsible Officer) within an organisation irrespective of the number of prescribers of CDs

The CDAO Role

The 2013 Regulations provide for the requirement that a designated body, either by itself or jointly in a group of other designated bodies, appoint a CDAO. The 2013 Regulations go on to set out the duties of a CDAO, which include:

1. Establishing and operating appropriate arrangements for securing the safe management and use of controlled drugs within their body or commissioned service, and reviewing, as appropriate, those arrangements;

2. Establishing and operating appropriate arrangements for monitoring and auditing the management and use of controlled drugs within their body or commissioned services, and ensuring these arrangements include provisions for assessing and investigating concerns and analysing and responding to incidents;

3. Establishing and operating arrangements for the monitoring and assessing of a relevant individuals connection with the management and use of controlled drugs; (define what is meant by monitoring and consider who monitors independent prescribing)

4. Ensuring relevant individuals, and those who require it, are receiving information, education or training on securing the safe management and use of controlled drugs;

The 2013 Regulations also outline the requirement for CQC/HIS to compile, maintain and publish from time to time, in such manner as it sees fit, a register of accountable officers of designated bodies. This is supported by the requirement for each designated body in England and Scotland to appoint a CDAO and register that person's details with CQC/HIS and notify of any change.

29. Does it remain appropriate that NHSE/SHB Regional CDAOs monitor CD prescribing for independent/private organisations? *

- ○ Yes
- ◉ No
- ○ No view

30. If you answered No, please elaborate.

Lack of capacity in NHS, see Q28

31. Does it remain appropriate for each designated body, or group of designated bodies, to nominate or appoint, a fit, proper and suitably experienced person to be its CDAO? *

- ◉ Yes
- ○ No
- ○ No view

32. If you answered No, please elaborate.

Please enter at most 150 characters

33. Do the duties of a CDAO, as outlined above, remain appropriate? *

- ◉ Yes

- ( ) No
- ( ) No view

34. If you answered No, please elaborate.

Please enter at most 150 characters

35. Does it remain appropriate for CQC/HIS to compile, maintain and publish national registers of CDAOs? *

- (•) Yes
- ( ) No
- ( ) No view

36. If you answered No, please elaborate.

Please enter at most 150 characters

37. **CDAO ONLY -** Are there any specific requirements in or omissions from the 2013 Regulations that limit your capacity to act as a CDAO and warrant further consideration?

- ( ) Yes
- ( ) No
- ( ) No view
- (•) Not applicable

38. If you answered Yes, please elaborate.

Please enter at most 150 characters

39. **CDAO ONLY -** Are there any specific requirements in the 2013 Regulations that you feel are too onerous or unnecessary in regard to your capacity to act as a CDAO and warrant further consideration?

- ○ Yes
- ○ No
- ○ No view
- ◉ Not applicable

40. If you answered No please elaborate

Please enter at most 150 characters

41. Does it remain appropriate to not appoint a CDAO where a designated body has fewer than 10 staff? *

- ○ Yes
- ◉ No
- ○ No view

42. If you have answered No please elaborate *

Irrespective of number of prescribers, each organisation should appoint a CDAO

43. Does it remain appropriate that the CDAO for the regular and reserve armed forces must hold the rank of Brigadier or above? *

- ○ Yes

- ○ No
- ◉ No view

44. If you answered No, what minimum rank should the CDAO for the regular and reserve armed forces have to hold?

Please enter at most 150 characters

Information Sharing for **Local NHS/CDAO Lead only -** please skip to 8 if not applicable.

The 2013 Regulations outline the requirement for local intelligence networks (LINs) to be established and operated by the NHS England and Health Boards in England and Scotland, respectively. The aim of LINs is to facilitate co-operation and information sharing between responsible bodies, which include designated bodies, in the area as regards the safe management and use of controlled drugs and local cases or issues relating to this.

LIN members are required to co-operate with other members on issues relating to the identification of cases in which action may need to be taken, the consideration of issues relating to taking action, and the taking of action in respect to matters arising in relation to the management or use of controlled drugs by individuals who are relevant persons as regards any member of the LIN.

Reinforce the importance of dynamic information sharing and behaviours; it is not just a periodic meeting

45. On average, how many LIN meetings do you convene a year?

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5 +

46. Do you feel that this number is sufficient?

- ○ Yes
- ○ No
- ○ I don't know

47. If you answered Yes, can you please elaborate why you think this is a sufficient number of LIN meetings

Please enter at most 150 characters

48. If you answered No, can you please elaborate why you do not think this is a sufficient number of LIN meetings.

Please enter at most 150 characters

49. On average, how many people attend each meeting?

Please enter at most 150 characters

50. If any attendees are not CDAOs, what are their job titles/roles?

Please enter at most 150 characters

51. How effective do you think LINs are in regard to securing the safe management and use of controlled drugs?

- ○ Very effective
- ○ Somewhat effective
- ○ Neither effective nor ineffective

- Somewhat ineffective
- Very ineffective

52. Please explain why you have chosen this response.

Please enter at most 150 characters

53. Do you think that LINs promote co-operation and information sharing between members, and learning from when things go wrong?

- Yes
- No
- Sometimes
- No view

54. If you answered No, can you please elaborate why you think the LINs do not promote these things and how information sharing and learning could be improved.

Please enter at most 150 characters

55. Do you think that LINs provide sufficient access to information you would otherwise be unable to obtain?

- Yes
- No
- No view.

56. If you answered No, can you please elaborate on what barriers you think exist in regard to obtaining information via LINs. How might relevant information be better shared?

Please enter at most 150 characters

57. Do you think that LINs are an effective method of sharing information on the wider use and diversion of controlled drugs in the area?

- ◯ Yes
- ◯ No
- ◯ No view

58. If you answered Yes, can you please elaborate on what barriers you think exist?

Please enter at most 150 characters

59. Do you think there are any organisations that are not currently included in LINs who would be useful to include?

- ◯ Yes
- ◯ No
- ◯ No view.

60. If you answered Yes, can you please elaborate on what organisations you think should be included.

Please enter at most 150 characters

61. Is it appropriate to allow Independent Health Clinics (IHCs) to appoint a CDAO and join a Local Intelligence Network (LIN).

- ◯ Yes
- ◯ No
- ◯ No view

62. If you answered Yes please elaborate

Please enter at most 150 characters

63. Have you ever experienced difficulties accessing information you feel you should have to carry out the statutory functions?

- ◯ Yes
- ◯ No
- ◯ No view

64. If you answered Yes, can you please elaborate on the difficulties that you have experienced and how might this be improved.

Please enter at most 150 characters

Information Sharing for **CDAOs** that did not complete section 7.

The 2013 Regulations outline the requirement for local intelligence networks (LINs) to be established and operated by the NHS Commissioning Board (known as NHS England) and Health Boards in England and Scotland, respectively. The aim of LINs is to facilitate co-operation and information sharing between responsible bodies, which include designated bodies, in the area as regards the safe management and use of controlled drugs and local cases or issues relating to this.

LIN members are required to co-operate with other members on issues relating to the identification

of cases in which action may need to be taken, the consideration of issues relating to taking action, and the taking of action in respect to matters arising in relation to the management or use of controlled drugs by individuals who are relevant persons as regards any member of the LIN.

65. Do you, or your organisation, attend Local Intelligence Network meetings (LINs)?

- ○ Yes
- ○ No
- ○ I don't know

66. How frequently do you, or your organisation, attend on average a year?

- ○ Never
- ○ Rarely
- ○ Often
- ○ Always

67. How helpful do you think your Local Intelligence Network(s) is(are) in regard to securing the safe management and use of controlled drugs?

- ○ Very helpful
- ○ Somewhat helpful
- ○ Neither helpful nor unhelpful
- ○ Somewhat unhelpful
- ○ Very unhelpful

68. Any additional comments?

Please enter at most 150 characters

69. Do you think that LINs promote co-operation and information sharing between members, and learning from when things go wrong?

- ○ Yes
- ○ No
- ○ No view

70. If you answered Yes, please can you provide an example.

Please enter at most 150 characters

71. If you answered No, can you please elaborate why you think the LINs do not promote these things and how information sharing could be improved.

Please enter at most 150 characters

72. How is information gained via the LINs shared within your organisation?

- ☐ Email
- ☐ Newsletter
- ☐ Meeting updates
- ☐ Other

73. Do you think that LINs provide sufficient access to information you would otherwise be unable to obtain / are an effective method of sharing information on the wider use and diversion/distribution(?) of controlled drugs in the area?

- ○ Yes

- ○ No
- ○ No view

74. If you answered No, can you please elaborate on what barriers you think exist in regard to obtaining information via LINs. How might relevant information be better shared?

    Please enter at most 150 characters

75. Do you think there are barriers that restrict the overall effectiveness of LINs?

    - ○ Yes
    - ○ No
    - ○ No view

76. If you answered Yes, can you please elaborate on what barriers you think exist.

    Please enter at most 150 characters

77. Do you think there are any organisations that are not currently included in LINs who would be useful to include?

    - ○ Yes
    - ○ No
    - ○ No view

78. If you answered Yes, can you please elaborate on what organisations you think should be included.

Please enter at most 150 characters

79. Have you ever experienced difficulties accessing information you feel you should have access to, when investigating when things go wrong?

- ◯ Yes
- ◯ No
- ◯ No view

80. If you answered Yes, can you please elaborate on the difficulties that you have experienced and how might this be improved.

Please enter at most 150 characters

Controlled Drug Incident Reporting for **Local NHS/HIS Lead only.** Please skip to 10 if N/A.

The 2013 Regulations provide the power for local lead CDAOs, who are operating LINs, to request periodic declaration and self-assessments from member bodies of the LIN regarding their use and management of controlled drugs. Furthermore, these CDAOs can request occurrence reports, on a quarterly basis or more frequently if warranted, that provide information regarding the concerns of that body in relation to the safe management and use of controlled drugs by a relevant individual - or the absence of such concerns.

81. Is there a mechanism for controlled drugs incidents occurring in your LIN area get reported to you?

- ◯ Yes
- ◯ No

82. If you answered No, where are incidents being reported instead?

Please enter at most 150 characters

83. Does it remain appropriate to request quarterly controlled drugs occurrence reports from members of your LIN?

- ○ Yes
- ○ No
- ○ I don't know

84. If you answered Yes, how useful is the information obtained? (Please provide examples)

Please enter at most 150 characters

85. if you answered No, please elaborate why this does not remain appropriate.

Please enter at most 150 characters

86. Does it remain appropriate to request periodic declarations and self-assessments from members of your LIN?

- ○ Yes
- ○ No
- ○ I don't know

87. If you answered Yes, how useful is the information obtained? (Please provide examples)

Please enter at most 150 characters

88. If you answered No, please elaborate why this does not remain appropriate.

Please enter at most 150 characters

89. In your opinion, to what extent have the 2013 Regulations contributed to increased reporting of controlled drugs incidences? [Scale]

- ○ Very decreased reporting
- ○ Decreased reporting
- ○ No change
- ○ Increased reporting
- ○ Very increased reporting
- ○ I don't know

90. If you answered **Very decreased reporting** or **Decreased reporting**, please elaborate why the 2013 Regulations have led to your response.

Please enter at most 150 characters

91. In your opinion, to what extent have the 2013 Regulations contributed to the sharing of information and learning from controlled drugs incidences? [Scale]

- ○ Very decreased sharing and learning
- ○ Decreased sharing and learning
- ○ No change
- ○ Increased sharing and learning
- ○ Very increased sharing and learning

- ◯ I don't know

92. Please provide examples of learning outcomes or elaborate why the 2013 Regulations have led to decreased sharing and learning, as appropriate.

Please enter at most 150 characters

93. In your opinion, to what extent have the 2013 Regulations contributed to increasing or decreasing the level of harm associated with controlled drugs incidences? [Scale]

- ◯ Very decreased level of harm
- ◯ Decreased level of harm
- ◯ No change
- ◯ Increased level of harm
- ◯ Very increased level of harm
- ◯ I don't know

94. If you answered I**ncreased level of harm** or **Very increased level of harm**, please elaborate how the 2013 Regulations have led to your response.

Please enter at most 150 characters

95. In your opinion, has there been an overall increase in the awareness of the requirements for the safe management and use of controlled drugs since the introduction of the Regulations in 2013? [Scale]

- ◯ Very decreased awareness
- ◯ Decreased awareness

- ◯ No change
- ◯ Increased awareness
- ◯ Very increased awareness
- ◯ I don't know

96. If you answered Very decreased awareness or Decreased awareness, please elaborate how the 2013 Regulations have led to your response.

Please enter at most 150 characters

97. Beyond data regarding controlled drugs incidence/occurrence reporting, is there any other data or evidence that you know of that could help inform our review of the 2013 Regulations?

- ◯ Yes
- ◯ No

98. If you have answered Yes, can you please elaborate. We may be in contact with you to discuss the information you can provide.

Please enter at most 150 characters

Controlled Drug Incident Reporting for **CDAOs** who did not complete section 9.

The 2013 Regulations provide the power for local lead CDAOs, who are operating LINs, to request periodic declaration and self-assessments from member bodies of the LIN regarding their use and management of controlled drugs. Furthermore, these CDAOs can request occurrence reports, on a quarterly basis or more frequently if warranted, that provide information regarding the concerns of that body in relation to the safe management and use of controlled drugs by a relevant individual - or the absence of such concerns.

99. How do you, or your organisation, report any controlled drugs incidents?

Please tick all that apply.

- [ ] Direct to Police Force / Controlled Drugs Liaison Officer
- [ ] Direct to your chief pharmacist
- [ ] Direct to your clinical leadership
- [ ] Direct to your "local lead" CDAO
- [ ] Direct to your Medication Safety Officer
- [ ] Direct to your professional Regulator
- [ ] Direct to Healthcare Improvement Scotland
- [ ] Via the CD Incident Reporting Tool (www.cdreporting.co.uk)
- [ ] Via a Datix reporting system
- [ ] Via Learn from patient safety events (LFPSE))
- [ ] Other

100. If you or your organisation do not report any controlled drugs incidents, can you please elaborate why.

Please enter at most 150 characters

101. Have you encountered any issues with the reporting of controlled drugs incidents to your "local lead" CDAO?

- ( ) Yes
- ( ) No

102. If you answered Yes, please elaborate.

Please enter at most 150 characters

103. Does it remain appropriate to provide a quarterly controlled drugs occurrence report to your “local lead” CDAO?

- ◯ Yes
- ◯ No
- ◯ I don't know

104. If you answered No, please elaborate why this does not remain appropriate.

Please enter at most 150 characters

105. In your opinion, have the 2013 Regulations contributed to your reporting of controlled drugs incidences? [Scale]

- ◯ Very decreased reporting
- ◯ Decreased reporting
- ◯ No change
- ◯ Increased reporting
- ◯ Very increased reporting
- ◯ I don't know

106. If you answered **Very decreased reporting** or **Decreased reporting**, please elaborate why the 2013 Regulations have led to your response.

Please enter at most 150 characters

107. In your opinion, have the 2013 Regulations contributed to increasing or decreasing your learning from controlled drugs incidences?

- ○ Very decreased learning
- ○ Decreased learning
- ○ No change
- ○ Increased learning
- ○ Very increased learned
- ○ I don't know

108. Please provide examples of learning outcomes or elaborate why the 2013 Regulations have led to decreased learning, as appropriate.

Please enter at most 150 characters

109. In your opinion, have the 2013 Regulations contributed to reducing or increasing the level of harm associated with controlled drugs incidences?

- ○ Very decreased level of harm
- ○ Decreased level of harm
- ○ No change
- ○ Increased level of harm
- ○ Very increased level of harm
- ○ I don't know

110. If you answered **Increased level of harm** or **Very increased level of harm**, please elaborate how the 2013 Regulations have led to your response.

Please enter at most 150 characters

111. In your opinion, has there been an overall increase or decrease in the awareness of the requirements for the safe management and use of controlled drugs since the introduction of the Regulations in 2013?

- ○ Very decreased awareness
- ○ Decreased awareness
- ○ No change
- ○ Increased awareness
- ○ Very increased awareness
- ○ I don't know

112. Beyond data regarding controlled drugs incidence/occurrence reporting, is there any other data or evidence that you know of that could help inform our review of the 2013 Regulations?

- ○ Yes
- ○ No

113. If you have answered Yes, can you please elaborate. We may be in contact with you to discuss the information you can provide.

Please enter at most 150 characters

Auditing and Investigations

The 2013 Regulations set out the requirement for CDAOs to audit and investigate as concerns the safe management and use of controlled drugs (including monitoring of prescribing responsibilities). In order to facilitate this, the 2013 Regulations provide powers to CDAOs to enter "relevant premises" for the purpose of securing the safe, appropriate and effective management and use of controlled drugs.

These "relevant premises", in England and Scotland, include (subject to inspection by the relevant CDAO) premises of:

England

1. relevant persons, as regards the NHS Commissioning Board (known as NHS England), that are not subject to inspection by the Care Quality Commission, the General Pharmaceutical Council or a CDAO of a regular or reserve force;
2. an NHS foundation Trust;
3. an NHS Trust;
4. a regular or reserve force, or of members of that regular or reserve force; and
5. an English independent hospital and premises of a person engaged in relevant activities on the hospital's behalf

Scotland

1. a Health Board;
2. any person or undertaking from which that person or undertaking provides a Health Board with services as part of the health service;
3. relevant persons, in the area of a Health Board, that are not subject to inspection by Healthcare Improvement Scotland, the Care Inspectorate or the General Pharmaceutical Council;
4. of a regular or reserve force, or of members of that regular or reserve force;
5. a Special Health Board, as previously specified in this questionnaire; and
6. a Scottish independent hospital and premises of a person engaged in relevant activities on the hospital's behalf

114. Do the 2013 Regulations give CDAOs adequate powers to investigate, and take prompt and effective action where appropriate, when concerns are raised about the safe management and use of controlled drugs?

- ○ Yes
- ○ No
- ◉ No view

115. If you answered No, please elaborate.

Please enter at most 150 characters

116. Do the “relevant premises” of the 2013 Regulations, outlined above, remain appropriate?

- ○ Yes
- ○ No
- ◉ No view

117. If you answered No, can you please elaborate on why they do not remain appropriate?

Please enter at most 150 characters

Objectives of the 2013 Regulations

118. To what extent do you think the 2013 Regulations have met their objective to “maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs” in relation to the safe management and use of controlled drugs? [Scale]

- ○ Have firmly met
- ◉ Have met
- ○ Have not met
- ○ Have firmly not met
- ○ No view

119. To what extent do you think the 2013 Regulations have met their objective to “protect patient and public health” in relation to the safe management and use

of controlled drugs?

- ○ Have firmly met
- ◉ Have met
- ○ Have not met
- ○ Have firmly not met
- ○ No view

120. To what extent do you think the 2013 Regulations have met their objective to "promote co-operation and information sharing between different local bodies and organisations" in relation to the safe management and use of controlled drugs?

- ○ Have firmly met
- ○ Have met
- ○ Have not met
- ○ Have firmly not met
- ◉ No view

121. To what extent do you think the 2013 Regulations have met their objective to "enable effective mechanisms to monitor and audit the use of controlled drugs" in relation to the safe management and use of controlled drugs?

- ○ Have firmly met
- ◉ Have met
- ○ Have not met
- ○ Have firmly not met

- ○ No view

122. To what extent do you think the 2013 Regulations have met their objective to "enable adequate powers to investigate, and take prompt and effective action where appropriate, when concerns are raised" in relation to the safe management and use of controlled drugs?

- ○ Have firmly met
- ○ Have met
- ○ Have not met
- ○ Have firmly not met
- ◉ No view

123. **Please elaborate in regard to each objective, as appropriate.**

Objective 1: Maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs

Objective 2: Protect patient and public health

Objective 3: Promote co-operation and information sharing between different local bodies and organisations

Objective 4: Enable effective mechanisms to monitor and audit the use of controlled drugs

Objective 5: Enable adequate powers to investigate, and take prompt and effective action where appropriate, when concerns are raised

Please enter at most 250 characters

124. How appropriate overall do you think the 2013 Regulations remain?

- ○ Very appropriate

- (●) Appropriate
- ( ) No view
- ( ) Inappropriate
- ( ) Very inappropriate

125. If you answered **Inappropriate** or **Very inappropriate**, please elaborate why you feel the 2013 Regulations no longer remain appropriate.

Please enter at most 150 characters

126. How effective overall do you think the 2013 Regulations have been in meeting the five primary policy objectives outlined above?

- ( ) Very effective
- (●) Somewhat effective
- ( ) Neither effective nor ineffective
- ( ) Somewhat ineffective
- ( ) Very ineffective

127. If you answered **Very ineffective** or **Ineffective**, please elaborate why you feel the 2013 Regulations were not effective in meeting the five policy objectives overall.

Please enter at most 150 characters

128. Do you think there have been any unintended consequences of the 2013 Regulations?

- (●) Yes

- ○ No
- ○ No view

129. If you answered Yes, please elaborate.

NHS teams monitoring and investigating CD related incidents across NHS and independent healthcare without capacity

130. Do you think the objectives of the 2013 Regulations could be achieved in another way which involves less onerous regulatory provision?

- ○ Yes
- ○ No
- ◉ No view

131. If you answered Yes, please elaborate.

Please enter at most 150 characters

132. **Do you have any comments to add that have not been covered by previous questions in this questionnaire?**

This call had a restrictive deadline preventing in depth analysis and the character limit of 150 on questions prevented relevant detail to be shared. Q6, 11 and 14 did not have an option to choose not applicable – which is our appropriate response.

out your password.