



Department  
of Health

# The Proposals to include Schedules 2 and 3 Controlled Drugs within the scope of the Electronic Prescription Service

Consultation Document

July 2014

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# The proposals to include Schedules 2 and 3 Controlled Drugs within the scope of the Electronic Prescription Service

## Consultation Document

**Prepared by: Department of Health, Medicines, Pharmacy and Industry – Pharmacy Team**

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# Executive summary

- The NHS Electronic Prescription Service (EPS) enables prescribers such as general practitioners (GPs) and practice nurses to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice. This makes the prescribing and dispensing process more efficient and convenient for patients.
- Controlled drugs (CDs) are a group of medicines that have the potential to be abused, but are essential to modern clinical care. The Misuse of Drugs Regulations 2001 divides CDs into five “schedules” according to the level of regulation required. Schedule 1 CDs have no proven therapeutic value and have potential for misuse and are therefore heavily regulated, whereas Schedule 5 CDs present little or no risk and are lightly regulated.
- Previous changes to the Misuse of Drugs Regulations in 2005 already allow for the electronic transmission of prescriptions for Schedules 4 and 5 CDs, but Schedules 2 and 3 CDs are currently out of scope.
- The main aim of this consultation and proposed changes to legislation is to enable the electronic prescribing of NHS prescriptions for Schedules 2 and 3 CDs. However, the Misuse of Drugs Regulations and medicines legislation cover both NHS and private prescriptions. These are prescribed in private care (non-NHS settings, such as private clinics), although some may be issued by a GP in an NHS consultation.
- This consultation document is structured as a two-part consultation:
  - 1) Do we enable NHS prescribed Schedules 2 and 3 CDs to be prescribed electronically (for England, this would be via EPS)?
  - 2) Do we enable privately prescribed Schedules 2 and 3 CDs to be prescribed electronically? If yes, with
    - an Advanced Electronic Signature (AES) alone; or
    - additional security (in England this would be via EPS)?
- Within the NHS in England, electronic prescriptions are sent by EPS, which has an AES (a unique electronic signature linked to the data being signed and the identity of the signer) and has multiple layers providing security. The other three countries in the UK, known as the Devolved Administrations (DAs) have yet to develop an NHS electronic system that utilises the AES provisions. The Department of Health is therefore working with colleagues to make sure the proposals are compatible with any developments they may pursue.

- The legislation that would need to be amended in England would be:
  - ✓ the Misuse of Drugs Regulations 2001;
  - ✓ the Human Medicines Regulations 2012;
  - ✓ the NHS (General Medical Services Contract) Regulations 2004 as amended;
  - ✓ the NHS (Personal Medical Services Agreement) Regulations 2004 as amended; and
  - ✓ the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013.

Corresponding changes will be applied to arrangements for the provision of primary medical services under Alternative Provider Medical Services contracts.

- The Misuse of Drugs Regulations 2001 requires that prescriptions for Schedules 2 and 3 CDs must express the total quantity of the drug prescribed in words and figures. It is thought that this requirement was introduced to make it harder for prescriptions to be tampered with, in particular, to have the quantity changed prior to presentation for dispensing and to make instructions of the prescriber clear to the pharmacist. If we enable Schedules 2 and 3 CDs to be prescribed electronically, we are also asking you whether we should continue to require the total quantity of the prescribed medicine to be written in words and figures or whether you wish us to remove this requirement for electronic prescriptions only (all paper prescriptions will still need to comply with this requirement).
- This consultation runs from 17 July to 9 October 2014. Please see page 19 for directions on how to respond to the consultation in the separate response form and online.

# 1. Introduction

1. In 2013, around 1 billion prescription items for human medicines were dispensed in the community in England and we expect this to continue to grow. In 2012/13, according to the NHS Business Services Authority (NHSBSA) data, approximately 13 million Schedules 2 and 3 Controlled Drugs (CDs) were prescribed in NHS primary care. Over the same period, approximately 36,000 Schedules 2 and 3 CDs were prescribed privately.
2. In 2004, *The Shipman Inquiry*<sup>1</sup>, a four-year Public Inquiry, led by Dame Janet Smith that examined the unlawful activities of Dr Shipman and the steps that needed to be taken to protect patients in the UK in the future, published its report on the regulation of CDs in the community. It identified weaknesses in the then current systems of control and in the ways in which those controls were operated. In response, a package of measures aimed at safeguarding patients and reducing the opportunity for diverting CDs without detection<sup>2</sup> were put in place.
3. One of the changes was the introduction of a special form for any private prescription of Schedules 2 and 3 CDs dispensed by community pharmacists. In England, these forms, along with NHS dispensed CD prescriptions have to be sent to the NHS Business Services Authority (NHSBSA) for interrogation and monitoring purposes. Records of these prescriptions are held on a central database hosted by the NHSBSA, so that prescription activity for Schedules 2 and 3 CDs can be monitored by NHS England and the NHSBSA. Another change was the introduction of Controlled Drugs Accountable Officers (CDAOs) to enable and monitor the safe management of CDs in their organisations. CDAOs are able to interrogate the NHSBSA database to look at all prescriptions for one prescriber. Individual prescribers can then be held to account for all their CD prescribing. Similar arrangements are in place in the DAs.
4. CDs are an important part of modern healthcare. Access to CDs for legitimate medicinal purpose is permitted, but subject to additional regulation to that of medical products - the Misuse of Drugs Regulations 2001. These Regulations carried forward from 1972 a regime of control around the prescribing, supplying or administering, safe custody, dispensing, record keeping, destruction and disposal of CDs. The chief purpose of these regulations is to prevent the diversion and misuse of CDs for patient and public protection.

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<sup>1</sup> <http://webarchive.nationalarchives.gov.uk/20090808154959/http://www.the-shipman-inquiry.org.uk/reports.asp>

<sup>2</sup> <http://www.official-documents.gov.uk/document/cm70/7014/7014.pdf>

5. All CDs are listed in one of five Schedules in the Regulations, according to their therapeutic usefulness and therefore need for legitimate access, as well as potential for misuse and the harm caused by that misuse (to both the individual and society). Schedule 1 CDs are subject to the greatest restrictions and Schedule 5 the least:
  - ✓ drugs within Schedule 1 generally have no proven therapeutic value, and have potential for misuse. They include cannabis and lysergic acid diethylamide (LSD);
  - ✓ schedule 2 contains opiate drugs, such as diamorphine, morphine, methadone and pethidine, as well as stimulants, such as amphetamines. These drugs have real therapeutic value, but may be addictive. Their use is quite strictly controlled, including special prescription requirements;
  - ✓ schedule 3 comprises barbiturates and some benzodiazepines, such as temazepam. Whilst less rigorously controlled than drugs in Schedule 2, they are also subject to special prescription requirements;
  - ✓ schedule 4 Part 1 contains most of the benzodiazepines, such as diazepam. Part 2 contains the anabolic and androgenic steroids that are only lightly regulated; and
  - ✓ schedule 5 includes preparations containing CDs, such as codeine or morphine, used in such low strength that they present little or no risk of misuse and can be sold over the counter.
6. In England, EPS is the means by which NHS electronic prescriptions can be generated, transmitted and received electronically. Prescriptions are transmitted via the NHS secure enclosed network (N3 network), making use of new technologies, such as smartcards and an AES. The EPS is a community-based IT service that provides a more efficient and consistently accurate system that is better able to cope with the continuing increase in prescription volumes. There are recognised benefits to both patients and healthcare professionals of the use of EPS. See Annex B for further information on the benefits.
7. Using EPS, patients can indicate a nominated dispenser, which enables that dispenser to receive the prescription information electronically. The dispenser is then able to prepare the prescription items in advance of the patients arriving to collect them. The dispenser is also able to send notifications of the dispensed prescriptions electronically to the NHSBSA for reimbursement purposes and for CDs, for monitoring and interrogation purposes.
8. Whilst the use of EPS in NHS primary care settings is still relatively low, there is evidence that the system operates effectively. As of 16 June 2014, a total of 2,206 GP practices (26% of all GP practices), 11,054 pharmacies (95% of all pharmacies) and around two thirds of dispensing appliance contractors (DACs) are now able to use EPS. Hence, there is scope for the wider deployment of the EPS system to deliver even greater benefits to prescribers, dispensers and patients.
9. Because Schedules 4 and 5 CDs are less open to abuse, the Misuse of Drugs Regulations were amended in 2005 when EPS was first introduced to enable the electronic prescribing of these CDs.



## Electronic Prescription Service Security

10. The Human Medicines Regulations 2012 (S.I. 2012/1916)<sup>3</sup> requires that an electronic prescription is signed with an AES. An AES is *more than* just an electronic signature and, as a result, provides an enhanced level of security.

### **Advanced Electronic Signature**

An AES is not a signature in the literal sense of the word. It is not the prescriber's signature scanned and transmitted electronically with the prescription details. Rather the AES is an industry standard defined in the EU Directive Electronic Signature Regulations at Article 2.2 as “an electronic signature that is uniquely linked to a signatory, and capable of identifying the signatory, and created by means the signatory can maintain under his sole control, and linked to the data being signed such that any change of the data is detectable”.

An AES is critical to the safe and secure operation of EPS because it ensures:

- the relevant contents of the message have not been changed since the signature was applied;
- the message was signed by the owner of the received certificate;
- the received digital certificate was issued by the Health and Social Care Information certificate authority set up to issue signing certificates;
- the signature was applied during the validity period for the received certificate.

11. However, EPS, which is used in the NHS in England, has additional security. The security is wider and operates across multiple layers. The layers combine to deliver a system that provides for the safe and secure transmission of NHS prescriptions. This is important for all medicines, but of particular significance for CDs. In addition to an AES, it uses a secure network, encryption, end point registration and smartcards.

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<sup>3</sup> <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

12. EPS is a highly secure electronic service, whereby:
- ✓ “N3” is the NHS-only secure network through which GPs and dispensaries link to the spine. This is the “Central Store” where electronic prescriptions are sent and from which they are drawn down. The spine itself is a secure data centre conforming to information security management standards;
  - ✓ messages are sent by encryption (the translation of data into a secret code) to protect data in transit;
  - ✓ it is not just the user who is registered to use the EPS system. The computer on which EPS is running is also registered with the network (endpoint registration); and
  - ✓ both prescribers and dispensers must have personal smartcards and use these to access the EPS system. Smartcards have private PIN numbers, like a bankcard. It is the smartcard which enables the prescriber to apply an AES to the prescription.
13. Systems are in place to prevent the replacement of a smartcard reader in the GP practice with a fraudulent one that reads off the PIN number (as happens for debit cards). As part of the terms and conditions of having an NHS smartcard, users must inform their smartcard Registration Authority if their card is lost or stolen. It can then be disabled.
14. In summary, when NHS prescriptions are prescribed and dispensed electronically through EPS, not only does the AES provide a layer of security, EPS adds additional layers of security over and above AES, to deliver a system that provides for the safe and secure transmission of all prescriptions.

## UK implications

15. At present, the added security of EPS is used for electronic NHS prescriptions in England. Northern Ireland currently do not utilise electronic transmission of prescription data in any way. In Wales and Scotland, whilst they have utilised 2D barcodes in various arrangements to make prescribing, dispensing and pricing processes safer and more efficient, there is still a reliance on a paper prescription. Thus, the provisions in the Human Medicines Regulations of using an AES are not utilised.
16. However, the Human Medicines Regulations impact on the whole of the UK; the Misuse of Drugs Regulations cover Wales and Scotland, as well as England. Northern Ireland has separate Misuse of Drugs Regulations, which mirror the 2001 Regulations. NHS legislation applies to England only. Therefore, DH has worked with DA colleagues to make sure the proposals are compatible with policy in each country.

## Private prescriptions

17. Private prescriptions can either be issued in non-NHS settings, or occasionally in NHS settings. An example of a non-NHS setting would be a prescription issued by a doctor

who works only from his/her private practice or clinic, does no NHS work and his/her patients only see him/her on a private basis.

18. The two main examples of a private prescription provided in an NHS setting are:
  - an NHS patient going on holiday to a country where the taking of anti-malarial medication is recommended. Therefore, they may get an NHS prescription for their NHS items and a private prescription for their anti-malarial medication; and
  - prescribing of products not available under the NHS. Schedules 1 and 2 of the (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (“2004 Regulations”) (as amended) set out NHS prescribing restrictions. Schedule 1 lists a number of drugs, medicines and other substances which GPs cannot prescribe on the NHS and Schedule 2 lists drugs, medicines and other substances which GPs can only prescribe on the NHS in certain circumstances. As part of their General Medical Services (GMS) consultations GPs can, if appropriate, prescribe products off these two lists privately. There are similar restrictions in patient consultations with primary medical services and alternative primary medical services GPs.
  
19. It is worth noting that private prescriptions can also be dispensed in non-NHS pharmacies, as well as NHS pharmacies.

## 2. Consultation

### Introduction

20. Traditionally, prescriptions for CDs were handwritten. However, in 2005, the Misuse of Drugs Regulations 2001 were amended to allow:
- paper prescriptions to be computer generated with a hand-written signature; and
  - electronic prescriptions with an AES, except for Schedules 2 and 3 CD prescriptions.
21. Schedules 2 and 3 CDs were excluded from the changes to Regulations due to greater confidence being required about how electronic prescriptions would work with particular reference to how safe and secure they would be.

### Current use of the NHS Electronic Prescription Service

22. Currently, although the volumes of use of the EPS are relatively low, the number of GPs and pharmacists using the system is growing. We have been advised that some GP practices are not utilising EPS because, where a patient has a prescription for CDs, as well as a prescription for non-CDs, the prescribing system may force the prescriber to issue the entire prescription on paper. Even where this does not happen, the prescriber has to choose whether to issue the entire prescription on paper or issue an electronic and a paper prescription (known as “split prescriptions”).
23. As well as being inefficient and reducing the benefits of EPS, splitting prescriptions has also raised issues around patient safety. If the patient or dispenser has not realised that there is a “split prescription”, the patient may only get one part of that prescription and not the complete medicines prescribed. They may get the electronic and not the paper prescription or vice versa.
24. The Department of Health, together with the Home Office and the Medicines and Healthcare products Regulatory Agency (MHRA), understand this practical difficulty and therefore are consulting on extending the scope of electronic prescribing for Schedules 2 and 3 CDs. The Home Office supports such a change if it can be assured that EPS will provide a similar, or better, level of protection from diversion and misuse.

25. Enabling electronic prescribing of Schedules 2 and 3 CDs in England will require amendments to the:
- Misuse of Drugs Regulations 2001 (cover the licensing of production, possession and supply of substances classified under the Misuse of Drugs Act 1971);
  - Human Medicines Regulations 2012 (specifies the description and classes of medicine which may be sold or supplied only in accordance with the prescriptions of an “appropriate practitioner” and may be administered only in accordance with the directions of such a practitioner);
  - NHS (General Medical Services Contract) Regulations 2004 as amended;
  - NHS (Personal Medical Services Agreement) Regulations 2004 as amended (both of these govern the provision of NHS primary medical services); and
  - NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 (govern the arrangements, in England, for the provision of pharmaceutical and local pharmaceutical services under Part 7 of the NHS Act 2006).

Corresponding changes will be applied to arrangements for the provision of primary medical services under Alternative Provider Medical Services contracts.

26. The relevant text of the current provisions can be found at Annex D

**Question 1**

***In the NHS, EPS can already be used for Schedules 4 and 5 CDs. Do we enable NHS-prescribed Schedules 2 and 3 CDs to be prescribed electronically - for England, this would be via EPS? Please give reasons for your choice - comments are specifically sought about security.***

## Private prescriptions

27. The main aim of this consultation and proposed changes to legislation is to enable the prescribing of NHS prescriptions for Schedules 2 and 3 CDs. However, the Misuse of Drugs Regulations and medicines legislation cover both NHS and private prescriptions.
28. We therefore need to consider whether we also enable the private prescribing of Schedules 2 and 3 CDs electronically. There are a number of different options to take. However, we consider there are two main options:
- 1) enable privately-prescribed Schedules 2 and 3 CD prescriptions using any system providing it has an AES; or

- 2) enable privately-prescribed Schedules 2 and 3 CD prescriptions to be electronic, **but** only where the prescriber/dispenser uses the NHS system; for England this would be EPS with its added security.

### Option 1

29. Whilst an AES has been deemed secure enough for non-CD prescriptions in England, for private CDs this would not utilise the additional security that we know EPS provides. We also do not have experience of AES only systems.
30. As explained above, all NHS and private Schedules 2 and 3 CD prescriptions must be submitted to the NHSBSA for interrogation purposes under the Misuse of Drugs (Amendment No.2) Regulations 2006.
31. The NHSBSA software used for electronic prescriptions would need to be compatible with any alternative AES only system that private sector prescribers would wish to employ. However, as there could be a number of alternative AES only systems, the cost to the NHSBSA of accommodating these could be very significant. Establishing a separate interrogation agency to manage private CD prescriptions from alternative AES only systems would also have practical and cost implications for the NHS.

### Option 2

32. If a private prescriber in a non-NHS setting and a private dispenser wish to take advantage of using EPS for Schedules 2 and 3 CDs, this would require them to have access to EPS. This would be at a cost to them. It would, however, provide the additional security of EPS above that of AES alone systems and would aid submission of prescriptions to the NHSBSA and associated CD monitoring requirements.
33. As stated above, EPS adds a further level of security to the electronic transmission of prescriptions, which is particularly valuable for the transmission of Schedules 2 and 3 CD prescriptions. Enabling private Schedules 2 and 3 prescriptions to be electronically transmitted via EPS could also mean more freedom of choice for patients (for example, someone prescribed a Schedule 2 or 3 CD in a private clinic in London being able to pick up their prescription at home in the West Midlands if they wish, rather than only being able to pick it up at a pharmacy with a system compatible with the clinic's system).
34. We recognise that there will be costs to non NHS prescribers and dispensers of using EPS. However, they would also incur costs if they were to use an AES only system. We do, of course, acknowledge that there are operational and governance issues to be worked through, for EPS in non-NHS settings.
35. On balance therefore we support option 2.

## Other UK countries

36. Within the NHS in England, electronic prescriptions are sent by EPS, which has added security above an AES. The DAs have yet to develop an NHS electronic system that utilises the AES provisions. The Department of Health is therefore working with colleagues to make sure the proposals are compatible with any developments they may pursue. Whilst electronic prescribing of private prescriptions is out of scope for the other DAs at this time, any changes to UK-wide legislation will need to be compatible with any developments they may pursue.

### **Questions:**

- 2. Do we enable privately-prescribed Schedules 2 and 3 CDs to be prescribed electronically? Please give reasons.**
- 3. We outline two options for enabling private prescriptions of Schedules 2 and 3 CDs to be prescribed electronically:**
- 1) enable privately-prescribed Schedules 2 and 3 CD prescriptions using any system providing it has an AES; or**
  - 2) enable privately-prescribed Schedules 2 and 3 CD prescriptions to be electronic, but only where the prescriber/dispenser uses the NHS system, for England this would be EPS with its added security.**

**Do you have a preference for either of these options? Please give reasons for your choice.**

- 4. Are there any other options we have not considered?**

## Requirement that prescriptions for Schedules 2 and 3 Controlled Drugs has the total quantity written in words and figures

37. The Misuse of Drugs Regulations 2001 requires that prescriptions for Schedules 2 and 3 CDs must express the total quantity of the drug prescribed in words and figures.
38. It is thought that this requirement was introduced for the following reasons: firstly, to make it harder for prescriptions to be tampered with, in particular, to have the quantity changed (for example, by increasing the quantity by adding a '0' on the end) prior to presentation for dispensing. Secondly, to make the instructions of the prescriber clear to the pharmacist, reducing ambiguity and the likelihood of human error particularly with regard to quantity (for example, where a '2' might look a '7').



39. As outlined above, EPS has several layers of security. It will be difficult for prescriptions to be intercepted and, if they are, the use of the AES will alert the dispenser that the prescription has been changed since the electronic signature was applied. However, human error such as the prescriber hitting the keyboard once too often is still a possibility. This could be mitigated by prescribing systems asking prescribers to validate the quantity before application of the electronic signature. ***Please note we do not intend that any change is made for paper prescriptions – they would still need to have the quantity written in words and figures.***

**Question 5**

***If prescriptions for Schedules 2 and 3 CDs are going to be enabled to be electronic, do you think that the total quantity should be written in words and figures or can this requirement be removed?***

***If yes, do you think the prescribing system should apply any safeguards to validate the quantity? Please give reasons for your view.***

## Business and equality impacts

40. The proposals set out in this consultation document for regulatory change are enabling and facilitative in that they would remove current legislative restrictions which prevent the use of electronic prescriptions for the purposes of prescribing Schedules 2 and 3 CDs. As the regulatory changes are enabling and facilitative, they do not create or impose direct costs on business. Paradoxically, this is an example of regulatory change enabling greater flexibility and delivering improvements to patients and business. We therefore do not consider a business impact assessment needs to be published.
41. NHS regulations governing the provision of primary medical care and community pharmaceutical NHS services set out the overarching framework and contractual requirements for delivery of these services. As such, they are outside the scope of the Government's Better Regulation initiative and the One in Two Out (OITO) rule (i.e. for every regulation introduced, two are removed).
42. The Home Office Misuse of Drugs Regulations 2001 are similarly out of scope of OITO. This is because controlled drugs legislation – the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations derived from that Act – is already in place and the legislative action of bringing additional drugs under control or making regulations in relation to those drugs – as is proposed here - does not trigger OITO.
43. Whilst the Human Medicines Regulations 2012 were considered in scope for OITO, the amendments proposed here involve a minor alteration to remove the restriction on the electronic prescribing of products subject to special medical prescription which are specified in Schedule 2 or 3 of the Misuse of Drugs Regulations and their equivalent in Northern Ireland. These changes simply extend the medicines that can be prescribed



## Consultation – including Schedules 2 and 3 CDs within the scope of EPS

using AES and the EPS and have no impact on the main provisions of those Regulations. They are therefore not considered to trigger OITO.

44. If you consider this policy does create a significant impact on any sector, we would welcome your views.
45. The Government is covered by the Equality Act 2010, and specifically, the Public Sector Equality Duty. The Duty covers the following protected characteristics: age; disability; gender reassignment; pregnancy and maternity; race (includes ethnic or national origins, colour or nationality); religion and belief (includes lack of belief); sex and sexual orientation.
46. There are three parts to the Duty and public bodies must, in exercising their functions, have due regard to all of them. They are:
  - the need to eliminate unlawful discrimination, harassment and victimisation;
  - advance equality of opportunity between people who share a protected characteristic and people who do not; and
  - promote good relations between people who share a protected characteristic and those who do not.
47. If GPs are able to prescribe Schedules 2 and 3 CDs as well as the patient's ordinary medicines, patients and the public will benefit. Enabling patients to pick their Schedules 2 and 3 CD repeat prescription up from the pharmacy may also improve access. Overall, we believe moving to EPS would support these three parts of the duty.

### **Questions:**

***We do not consider a business impact assessment is needed.***

***6. Do you consider there are any significant impacts on any sector involved in this policy?***

***7. Are you aware of any equality issues or of any particular group for whom the proposed policy could have a detrimental effect?***

### 3. Summary of consultation questions

**Question 1: In the NHS, EPS can already be used for Schedules 4 and 5 CDs. Do we enable NHS prescribed Schedules 2 and 3 CDs to be prescribed electronically - for England, this would be via EPS? Please give reasons for your choice - comments are specifically sought about security.**

**Question 2: Do we enable privately-prescribed Schedules 2 and 3 CDs to be prescribed electronically? Please give reasons.**

**Question 3: We outline two options for enabling private prescriptions of Schedules 2 and 3 CDs to be prescribed electronically:**

- 1) enable privately-prescribed Schedules 2 and 3 CD prescriptions using any system providing it has an AES; or**
- 2) enable privately-prescribed Schedules 2 and 3 CD prescriptions to be electronic, but only where the prescriber/dispenser uses the NHS system, for England this would be EPS with its added security.**

**Do you have a preference for either of these options? Please give reasons for your choice.**

**Question 4: Are there any other options we have not considered?**

**Question 5: If prescriptions for Schedules 2 and 3 CDs are going to be enabled to be electronic, do you think that the total quantity should be written in words and figures or can this requirement be removed?**

**If yes, do you think the prescribing system should apply any safeguards to validate the quantity? Please give reasons for your view.**

**Question 6: We do not consider a business impact assessment is needed. Do you consider there are any significant impacts on any sector involved in this policy?**

**Question 7: Are you aware of any equality issues or of any particular group for whom the proposed policy could have a detrimental effect?**

# Responding to this consultation

## Consultation process

The consultation is being run, as far as is practical, in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). The closing date for the consultation is **9<sup>th</sup> October 2014**.

There is a response form on the GOV.UK website which can be printed and sent by post to: **Gillian Farnfield, Rm 453D Skipton House, 80 London Road, London, SE1 6LH**

Completed response forms can also be sent electronically by e-mail to:  
[gillian.farnfield@dh.gsi.gov.uk](mailto:gillian.farnfield@dh.gsi.gov.uk)

Alternatively you may also complete the online consultation response document at:  
<http://consultations.dh.gov.uk>

It will help us to analyse the responses if respondents fill in the online consultation response document but responses that do not follow the structure of the questionnaire will be considered equally. It would also help if responses were sent in Word format, rather than in pdf format.

## Criteria for consultation

This consultation follows the Government Code of Practice, in particular we aim to:

- Formally consult at a stage where there is scope to influence the policy outcome;
- Consult for a sufficient period.
- Be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- Ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- Keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- Analyse responses carefully and give clear feedback to participants following the consultation;
- Ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.
- The full text of the code of practice is on the Better Regulation website at:  
[www.bis.gov.uk/policies/better-regulation/consultation-guidance](http://www.bis.gov.uk/policies/better-regulation/consultation-guidance)

## Annex A – List of consultees

Association of Chief Police Officers

British Medical Association

Care Quality Commission

Devolved administrations

NHS England

NHS Business Services Authority including NHS Protect

Pharmaceutical Services Negotiating Committee

## Annex B – Electronic Prescription Service

1. The EPS is a community-based IT service that provides a more efficient and consistently accurate system that is better able to cope with the continuing increase in prescription volumes. It delivers tangible benefits for: patients (increasing their choice and convenience), community-based prescribers (e.g. GPs), dispensers (e.g. pharmacists) and their staff.
2. EPS applies to all NHS prescribers including doctors, Primary Dental Practitioners, and all non-medical prescribers (community practitioner Nurse Prescribers and supplementary prescribers).
  - a) *Benefits to Patients* - while the extent of patient benefits will depend on individual circumstances, they include:
    - more convenient service with a reduction in trips to the GP practice to collect a paper prescription, especially relevant for patients on repeat medication;
    - greater freedom of choice - EPS makes it simpler for a patient to use a community pharmacy convenient to them e.g. one that is convenient to where they live, work or shop; and
    - potential to reduce pharmacy waiting times as dispensers have the opportunity to prepare a prescription in advance of the patient arriving.
  - b) *Benefits to Prescribers*
    - reduction in workload at GP practices generated by patients collecting prescriptions. It also makes it easier to use repeat dispensing (which could reduce the workload generated by patients frequently requesting repeat prescriptions);
    - ability to sign prescriptions electronically potentially resulting in a considerable reduction in workload and making the prescribing process more efficient for GPs;
    - ability for GPs to electronically cancel prescriptions until they are dispensed, potentially leading to increased confidence in electronic repeat dispensing; and
    - where a GP practice operates a prescription collection service, staff no longer needing to sort (or post) prescriptions, saving both time and resource.
  - c) *Benefits to Dispensers*
    - reduction in the need for pharmacy staff to re-key prescription information, freeing dispensing staff from the associated work;
    - as nominated electronic prescriptions may be received prior to the patient arriving, EPS streamlines their workflow by preparing medications in advance. It also helps to manage stock control more effectively and order out-of-stock items in a timely manner;

## Consultation – including Schedules 2 and 3 CDs within the scope of EPS

- nomination means that dispensing contractors who offer prescription collection services are no longer required to physically collect prescriptions from GP practices for patients who have nominated them; and
- dispensers are able to manage submission of reimbursement endorsements electronically for electronic prescriptions, reducing the volume of paper to be sorted and posted at the end of each month.

### 3. EPS supports the following prescribing models:

- acute prescriptions (for example a one off prescription for a generally healthy person);
- repeat prescriptions; and
- repeatable prescriptions (repeat dispensing).

### 4. The following prescribing models are not supported and, therefore, still require a hand signed FP10 paper prescription:

- scenarios where the prescriber does not have access to the EPS (for example home visits and out of hours);
- personal administration of medication;
- private prescriptions;
- bulk prescriptions (Drug Tariff Part VIII note 9) for a school or institution;
- scenarios when the patient chooses not have an electronic prescription;
- where a patient has not nominated a dispensing contractor;
- where the prescription contains one of the limited number of items that are not directly expressible using the NHS Dictionary of Medicines and Devices; and
- instalment prescriptions.

# Annex C – Electronic Prescription Service Security

## Key layers of security within EPS

- EPS servers and associated systems are housed in secure data centres. Data centres conform to the BSI information security management code of practice, referred to internationally as ISO27001;
- In contrast to other services such as internet banking, EPS is only available over the N3 network and is not accessible from the Internet thus limiting exposure. Any organisation requiring an N3 connection has to complete the Information Governance Toolkit which is aligned with the ISO27001 security standard. In addition there are further security measures including that:
  - ✓ two-factor authentication is required to access EPS utilising the NHS Smartcard solution. NHS Smartcards are issued to healthcare professionals via a registration process, which meets eGIF Level 3. All authentications to the system are performed at eGIF Level 3 which provides a high degree of assurance as to the identity of the user;
  - ✓ industry standard encryption is utilised to protect data in transit over the network. This is with the use of SSL/TLS and helps prevent unauthorised interception and tampering;
  - ✓ advanced electronic signatures: Under The Medicines for Human Use (Prescribing) Order 2005 (Statutory Instrument 2005 No. 765) and the National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005 must be signed with an advanced electronic signature that enables the electronic prescription to become the legal entity allowing the dispensing contractor to supply medication to the patient. To meet the requirements defined by the Electronic Signatures Regulations 2002 which defines an electronic signature - which is uniquely linked to the signatory: capable of identifying the signatory; which is created using means that the signatory can maintain under his sole control, and which is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable. The existing smartcard model meets the legal requirement to enable the electronic prescriptions to be signed with an advanced electronic signature;
  - ✓ multi-tier architecture utilising firewall technology provides a layered security defence;
  - ✓ periodic penetration testing is carried out on EPS. This is where a trained security professional utilises “hacking” techniques to try to gain access to the system to identify potential weaknesses;
  - ✓ before allowing a user to sign a prescription the system validates the user has been assigned the relevant roles to allow them to prescribe;
  - ✓ before access is allowed to electronically transmitted prescription the end point user has to be recognised as being accredited within the HSCIC Spine directory service;
  - ✓ before dispensing the electronic signature is checked to ensure the content of the message it contains has not changed since the prescriber applied it; and
  - ✓ verifies the dispenser. The dispenser can only receive the prescription after the system has made sure he is authorised to receive it.

## Consultation – including Schedules 2 and 3 CDs within the scope of EPS

All of the above measures are combined to provide a concept of “defence in depth” and as such provide a secure platform for the delivery of the Electronic Prescription Service.



## Annex D – Text of current provisions in relevant legislation

### ***The Home Office Misuse of Drugs Regulations 2001 (SI 2001/3998) as amended by SI 2006/1450***

- 15** (1) Subject to the provisions of this regulation, a person shall not issue a prescription containing a controlled drug other than a drug specified in Schedule 4 or 5 or temazepam unless the prescription complies with the following requirements, that is to say, it shall-
- (a) be written so as to be indelible, be dated and be signed by the person issuing it with his usual signature
  - (b) except in the case of a health prescription, specify the address of the person issuing it;
  - (c) if issued by a dentist, have the words “for dental treatment only” written on it and, if issued by a veterinary surgeon or a veterinary practitioner, have a declaration written on it that the controlled drug is prescribed for an animal or herd under his care;
  - (d) specify the name and address of the person for whose treatment it is issued or, if it is issued by a veterinary surgeon or veterinary practitioner, of the person to whom the controlled drug prescribed is to be delivered
  - (e) specify the dose to be taken and –
    - i. in the case of a prescription containing a controlled drug which is a preparation, the form and, where appropriate, the strength of the preparation, and either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied;
    - ii. in any other case, the total quantity (in both words and figures) of the controlled drug to be supplied;
  - (f) in the case of a prescription for a total quantity intended to be supplied by instalments, contain a direction specifying the amount of the instalments of the total amount which may be supplied and the intervals to be observed when supplying.
- (1A) A person shall not issue a prescription other than a health prescription containing temazepam unless it is written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing and it specifies the prescriber identification number and the address of the person issuing it.
- (1B) Nothing in this regulation prevents the issue of a prescription, other than a health prescription, which is not written on a prescription form provided by a Primary Care Trust or equivalent body for the purposes of private prescribing, containing a controlled drug other than a drug specified in Schedule 4 or 5, where the person issuing the prescription believes on reasonable grounds that the drug will be supplied by a pharmacist in a hospital.”

- (2) In the case of a prescription issued for the treatment of a patient in a hospital or nursing home, it shall be a sufficient compliance with paragraph 1(d) if the prescription is written on the patient's bed card or case sheet.

***The MHRA's Human Medicines Regulations (2012) (as amended) – SI 2012/1916***

**Electronic prescriptions**

- 219** (1) This regulation applies to a prescription that is not a health prescription for a product subject to special medical prescription.
- (2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an appropriate practitioner other than an EEA health professional if—
- (a) conditions A and B in regulation 217 are not met; but
- (b) the conditions in paragraph (4) of this regulation and conditions C to E in regulation 217 are met.
- (3) A prescription only medicine is also sold or supplied in accordance with a prescription given by an EEA health professional if—
- (a) conditions B and C in regulation 218 are not met, but
- (b) the conditions in paragraph (4) of this regulation and conditions A and D to F in regulation 218 are met.
- (4) The conditions mentioned in paragraphs (2)(b) and (3)(b) are that the prescription is—
- (a) created in electronic form;
- (b) signed with –
- (i) an advanced electronic signature in the case of a prescription falling within paragraph (2), or
- (ii) an electronic signature in the case of a prescription falling within paragraph (3), and
- (5) In this regulation “advanced electronic signature” means an electronic signature that is—
- (a) uniquely linked to the person (“P”) giving the prescription;
- (b) capable of identifying P;
- (c) created using means that P can maintain under P's sole control; and
- (d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable.

***The NHS (General Medical Services Contracts) Regulations 2004 (as amended) – SI 2004/291***

- 39 (6) In a case of urgency a prescriber may request a chemist to dispense a drug or medicine before a prescription form or repeatable prescription is issued, only if-
- (a) that drug or medicine is not a Scheduled drug;
  - (b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971**(b)**, other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001**(c)**.
- 42 (4) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on a repeatable prescription a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, but may, subject to regulation 24(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

***The NHS (Personal Medical Services Agreements) Regulations 2004 (as amended) – SI 2004/627***

- 38 (6) In a case of urgency a prescriber may request a chemist to dispense a drug or medicine before a prescription form or repeatable prescription is issued, only if-
- (a) that drug or medicine is not a Scheduled drug;
  - (b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971**(b)**, other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001**(c)**.
- 41 (4) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on a repeatable prescription a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, but may, subject to regulation 24(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

***Corresponding changes to arrangements for provision of primary medical services under Alternative Provider Medical Services contracts.***

**The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended) – SI 2013/349**

**SI 2013/349 – paragraphs 5, 6 and 8 of Schedule 4 (Pharmacists)**

**Dispensing of drugs and appliances**

- 5 (3) Subject to the following provisions of this Part, where
- (a) any person presents to P a non-electronic repeatable prescription which contains-
    - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971<sup>(4)</sup>, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001<sup>(5)</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,
    - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference “SLS”,
  - (4) P must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

**Urgent supply without a prescription**

- 6 (1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist (P) to provide a drug or appliance.
- (2) P may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that-
- (b) in the case of a request for a drug, the drug is neither-
    - (i) a Schedule drug, nor
    - (ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 of the Misuse of Drugs Regulation 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations);

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<sup>(4)</sup> 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

<sup>(5)</sup> S.I. 2001/3998 - Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

## Providing ordered drugs or appliances

8. If the order-
- (a) is an order for a drug; but
  - (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 of the Misuse of Drugs Regulation 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations), and does not prescribe its quantity, strength or dosage, P (in this context, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care P considers to be appropriate, and, subject to sub-paragraph 7, in such quantity as P considers to be appropriate for a course of treatment for a period not exceeding 5 days.

### *SI 2013/349 – paragraph 2 of Schedule 6 (dispensing doctors)*

## Dispensing of drugs and appliances ordered by another prescriber

- 2 (3) Subject to the following provisions of this Schedule, where-
- (a) any person presents to D a non-electronic repeatable prescription which contains-
    - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971<sup>(6)</sup>, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001<sup>(7)</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber other than D,
    - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than D and including the reference “SLS”,
    - (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than D, or
    - (iv) an order for a restricted availability appliance, signed by a prescriber other than D, and including the reference “SLS”,and also presents an associated batch issue;
  - (4) D must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001,

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<sup>(6)</sup> 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

<sup>(7)</sup> S.I. 2001/3998 - Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

**SI 2013/349 – paragraph 3, 4 and 6 of Schedule 7 (LPS Chemists)**

**Dispensing**

3. (2) Where an LPS scheme includes the provision of repeat dispensing services, subject to any provisions of repeat dispensing services, subject to any provisions of the LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule, where-
- (a) any person presents to C a non-electronic repeatable prescription which contains-
- (i) an order for a drug, not being a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971<sup>(8)</sup>, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001<sup>(9)</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,
- (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference “SLS”,
- (3) C must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

**Urgent supply without a prescription**

- 4 (b) the drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

**Providing ordered drugs or appliances**

- 6 (4) If the order-
- (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971<sup>(10)</sup>, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001<sup>(11)</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

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<sup>(8)</sup> 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

<sup>(9)</sup> S.I. 2001/3998 - Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

<sup>(10)</sup> 1971 c.38; see section 2(1)(a) of that Act, which defines “controlled drug” for the purposes of that Act.

<sup>(11)</sup> S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.