Revalidation and GDPR

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Why do we have a new revalidation framework?

Public expectations

Encourage reflection on learning and practice

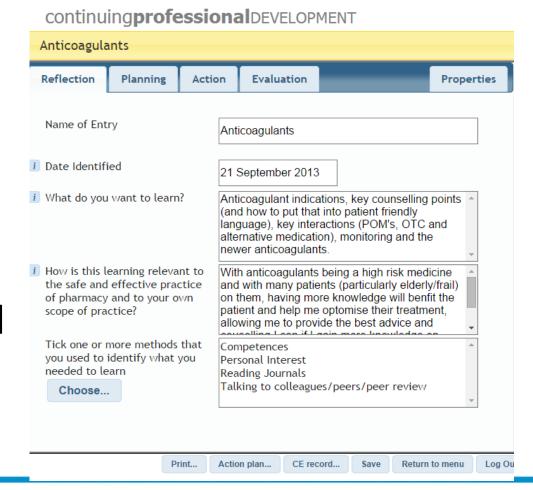
Increase the focus on outcomes for those using the pharmacy services





How do we currently complete CPDs?

- Record online uptodate.org.uk
- Complete nine CPD entries for each year of registration
- Submit as part of 'Call and Review' request







New revalidation framework

Four CPD records

One record of peer discussion

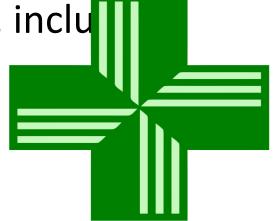
One reflective account





Who does it affect?

- All GPhC registered pharmacists and pharmacy technicians
- Not affected by individual factors, inclu
 - Part-time employment
 - Non patient-facing roles
 - Living/working outside of the UK
- Does not apply to pre-registration students







Timeline – what's happened so far

2010 – proposal began for developing revalidation

2014 – Advisory group set up made up of representatives from over 30 organisations, including the NPA

2014 to 2017 – Research, testing, piloting, and evaluating. This included a 12 Week consultation to obtain feedback from pharmacists and pharmacy technicians

December 2017 - Council approved the new revalidation framework





Timeline – what lies ahead

Early February 2018

- Framework to be launched by the GPhC
- Email to be sent to all registrants to look out for a letter which will be sent in April
- 30th March 2018
 - Go live date for revalidation recording of CPDs can begin
 - Go live date for new online portal
 - CPDs on the old portal will become read-only registrants can print off old CPD entries
- 6th June 2018
 - Old portal goes offline ensure you have downloaded previous
 CPD entries





Revalidation framework timeline

- Implemented from 30 March 2018
- If your registration expires on 31 December 2018:
- You are required to submit only **four** CPD entries as part of your renewal – can only be submitted once your renewal window opens on 1st September 2018
- When your registration expires on 31 December 2019, you will be required to submit all six records as part of your renewal which will include one reflective account and one peer discussion





What will happen to my previous CPD records on the 'uptodate.org' system?

- Under new framework only submit records for the previous year
- Records on the uptodate.org system will not be transferred to the new online portal
- Ability to print a copy of records on the uptodate.org system
- Uptodate.org system will turn off on 6th June 2018





CPD records

- Each year, pharmacists and pharmacy technicians must submit four CPD entries
 - At least two must be planned learning activities







Top tips for completing revalidation records: CPD

- ✓ Include a specific learning objective
- ✓ Make it clear how the learning is relevant to your role
- ✓ Explain how the learning will affect individuals using your services
- ✓ Describe learning activities
- ✓ Explain how the learning has been applied
- ✓ Provide examples of the benefits of the learning to service users
- ✓ Provide any feedback or evidence
- ✓ Include any next steps







Leyla's CPD – planned

- What are you planning to learn?
- The new legislation surrounding schools obtaining adrenaline auto-injectors from 1 October 2017
- This learning will ensure I am aware of who can request, the requirements of such requests, how
 to process and record requests and allow me to make a prompt supply to the school, in order to
 maintain their emergency stocks
- How are you planning to learn it?
- I am planning to use the NPA Member News update, NPA "Adrenaline auto-injectors supply to schools: FAQs" to learn the changes to the Human Medicines Regulation 2012
- Give an example of how this learning has been benefited the people using your services.
- This learning has allowed me to make a prompt supplies of adrenaline auto-injector stock to schools, so that if a child requires administration in an emergency there is stock available
- I have been able to help schools check the stock they currently have is still within the expiry date and have advised schools on how to produce a legally valid requisition





Leyla's CPD – unplanned

- Describe an unplanned event or activity that enabled you to learn something new or refresh my knowledge or skills.
- Whilst dispensing a prescription for amoxicillin to a patient on regular methotrexate, an interaction flagged on the system – I was not aware of an interaction and the PMR system provided minimal information
- Using a range of resources to find out more, such as the severity of the interaction, what could be the outcome and any practical/clinical actions needed
- I used product SPCs, BNF and Stockleys to research and found that amoxicillin leads to reduced clearance of methotrexate and potential acute methotrexate toxicity
- Give an example of how has this learning benefited the people using your services.
- I was able to discuss the interaction with the prescriber and provide advice and my opinion on how to proceed, including the options to continue with the prescription but increase monitoring to twice weekly
- This ensured the patient would be closely monitored during treatment and any signs of toxicity would be picked up before any harm was caused





Peer discussion

- Each year, pharmacy professionals must submit one record of a peer discussion
- A peer discussion is an activity undertaken through engagement with others, involving reflection on learning and practice



 However a peer review is a learning and development activity that encourages engagement and involves an assessment of performance

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Peer discussion



Peer discussions should:

Be open and honest

Relate to activities from the past year

Help you reflect on your practice to help make improvements





Top tips for completing revalidation records: peer discussion

- ✓ Include a description of why this peer was chosen
- ✓ Explain how the peer discussion has helped you reflect on your practice
- ✓ Describe changes made to your practice as a result
- ✓ Provide examples of how the changes implemented have positively impacted and benefited your service users
- ✓ Be between 200- 400 words (but there is no minimum or maximum)





Leyla's record – peer discussion

- Describe how this peer discussion changed your practice for the benefit of the people using your services
- My peer discussion was undertaken with the NPA Chairman, Ian Strachan I chose Ian as my peer as he has an insight to my work stream
- My peer discussion focussed on improving patient safety in community pharmacy, as part of my role as Medication Safety Officer - we also discussed examples of patient safety work I have conducted and the feedback from my peer has helped me identify areas for improvement
- I have shared this learning with other pharmacists in the NPA Pharmacy Team, as I
 now plan to delegate more roles to other teams members, where possible
- Overall, this will help improve future patient safety projects and therefore improve the resources and support I provide the NPA members





Reflective account

- Each year, pharmacists and pharmacy technicians must submit one record of a reflective account
- A reflective account is an activity designed to encourage pharmacists and technicians to think about the way in which they work in relation to the GPhC standards







GPhC Standards

- Provide person-centred care
- Work in partnership with others
- Communicate effectively
- Maintain, develop and use their professional knowledge and skills
- Use professional judgement
- Behave in a professional manner
- Respect and maintain the person's confidentiality and privacy
- Speak up when they have concerns or when things go wrong
- Demonstrate leadership





Reflective account

The reflective account should include:

A summary of you practice from the past year



How one of more of the GPhC standards for pharmacists and pharmacy technicians have been met



Examples of how individuals using your services have benefited





Top tips for completing revalidation records: reflective account

- ✓ Describe the setting of your practice and your main roles
- ✓ Include a description of the typical users of your service(s)
- ✓ Explain how you have met the GPhC standard(s) for pharmacy professionals
- ✓ Include examples
- ✓ Include any feedback or evidence







Leyla's record – reflective account

- Provide a reflective account of how you met one or more of the Standards for Pharmacy Professionals – this particular record is ion regards to Standard 3 "communicate effectively".
- I am the NPA Chief Pharmacist /Director of Pharmacy and manage a team of pharmacists
- My service users include; NPA members, superintendents, the NPA board and other healthcare professionals and health organisations
- Effective communication is vital in my role everyday in a wide variety of situations such as discussing issues/advising my team and other healthcare professionals
- A good example of my ability to effectively communicate discussing the top patient safety concerns, analytics of the patient safety reports submitted to the NPA and ongoing legal cases with the other MSO at the Patient Safety Group
- We all discussed these topics and were able to communicate ideas with each other in order to then cascade the concerns to community pharmacists and in the best manner





Review of records

- All records go through an automatic checking process
- Minimum of 2.5% of registrants selected for full review
- Reviewed against set criteria
 - Core
 - Feedback







Review of records

- Undertaken by a pharmacy professional and lay reviewer
- May be required to submit further information to verify records
- Tailored feedback provided
- No feedback score







NPA resources

- Suite of supportive resources will be made available for members
 - Overview and FAQs
 - Templates
 - Examples and case studies
 - Suggested reading and learning topics
- NPA will aim to act as a 'peer' or contact point for potential peers to assist in making arrangements for a peer discussion





Next steps

- Start to think about CPD topics use the NPA resources for ideas
- 2. Begin thinking about finding a peer think who would be most suitable?
- 3. Watch out for the new GPhC online portal once it is available, become familiar with the system
- 4. Plan a **timeline** by which you want to have each of the six records completed by, in time for your registration renewal date **be prepared**





FAQs



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How long will it take to complete the six records and when do these need to be submitted by?

- For CPD records, approximately 4.5 hours
- For the peer discussion (including arranging the discussion and the write up) 2 to 5 hours
 - The peer discussion itself is expected to be around 30 minutes to one hour
- For the reflective account, approximately an hour
- These records must be submitted each year, at the same time registration renewal is completed





If I miss the submission deadline or I cannot complete/submit all the records, will I be able to renew my registration?

- When renewing registration, registrants must declare that you will comply with the revalidation framework
- If unable to submit some/all records inform GPhC in advance of renewal
- Dependant on individual circumstances/reasons, may still be able to renew registration
- Without good reasons, you will enter a remediation process





How will the records submitted be reviewed and will feedback be provided?

- All submissions undergo an automatic check to ensure all records are complete
- Sample of submissions are selected for review
 - Informed if selected for review and when to expect the outcome
 - Reviewed against GPhC criteria
 - Peer contacted
 - Undertaken by pharmacy professional and lay reviewer
 - A feedback report will be provided





Who are the 'service users'?

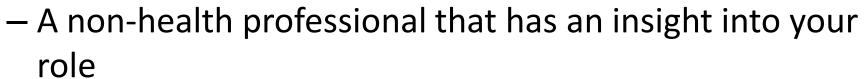
- Dependent on the pharmacists and pharmacy technicians area of practice
- This can include:
 - Patients
 - Patient family and carers
 - Health and non-health professional colleagues
 - Students/trainees
 - Organisations
- Include direct and indirect recipients





Who can be a peer and how do I find a peer?

- A number of examples:
 - Another pharmacist/technician
 - Another health professional



- Someone you work with
- A group of individuals in a similar role
- Not an individual with which you have a close relationship with (such as a family member or friend)







How is a reflective account different from a CPD record?

 Reflective account: type of learning that focuses on how the individual meets one or more of the GPhC standard(s) for pharmacy professionals

 CPD entries: type of learning that does not need to focus on the GPhC standards – but it must be relevant to the individuals practice





What will happen to my previous CPD records on the 'uptodate.org' system?

- Under new framework only submit records for the previous year
- Records on the uptodate.org system will not be transferred to the new online portal
- Ability to print a copy of records on the uptodate.org system
- Uptodate.org system will turn off on 30 June 2018





Questions?







GDPR (what we know so far)





Data protection law: what is changing?

Data Protection
Directive



General Data
Protection Regulation
(GDPR)

Applies from 25th May 2018

Data Protection Act 1998 (DPA)



Data Protection Bill 2017

Currently passing through UK parliament

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Brief overview of the GDPR





GDPR: brief overview

- Implementation date: 25 May 2018
- Many concepts and principles similar to existing DPA
- New elements and significantly enhanced requirements
- Key changes include:
 - Updated data protection principles and scope
 - Updated conditions for processing data
 - New rules regarding consent
 - Enhanced data subject rights
 - New, specific legal responsibilities for organisations processing children's data
 - New obligations for data controllers and processors
 - New addition of the 'accountability principle' and the role of the 'Data Protection Officer"
 - Greater regulation and enforcement





| Data Protection Act | The General Data Protection Regulation |
|--|---|
| Only applicable in UK | Applies to all EU countries |
| No requirement for a data protection officer (DPO) | Appointment of a data protection officer (DPO) required for certain organisations |
| Consent: does not necessarily require positive opt-in | Consent: must be specific, positively opted-in and not implied |
| Covers personal data and sensitive personal data | Covers personal data and special categories of data (which includes genetic/biometric data, location data and online identifiers) |
| Responsibility lies predominantly with the data controller | Responsibility lies with both the data controller and processor |
| Comparably less accountability | Accountability principle explicitly defined |
| Subject access requests: £10 and within 40 days | Subject access request: free of charge and within 30 days |





GDPR: personal data

- GDPR applies to personal data
- Personal data includes:
 - Information manually held in filing systems
 - Automated personal data
 - IP address
- 'Special categories of personal data'
 - Similar to the concept of sensitive personal data under the current DPA
 - GDPR includes genetic/biometric data where it is processed to identify an individual





GDPR: application

GDPR applies to:

All data controllers and data processors

- A data controller determines how and why personal data is processed
- A data processor carries out the processing on behalf of the data controller

Exemptions to GDPR:

Certain activities are exempt from GDPR requirements including those:

- Covered by the Law Enforcement Directive
- Used for national security purposes
- Carried out by individuals purely for personal/household activities





GDPR: Lawful basis for processing

- 1. Data subject provides **consent** to the processing of their personal data for one/more specific purposes
- 2. Data processing is necessary due to a **contract** in place or prior to an individual entering into a contract
- 3. Data processing is necessary for compliance with a **legal obligation** to which the controller is subject
- 4. Data processing is necessary to **protect** the vital interests of the data subject /another natural person
- 5. Data processing is necessary for the **performance of a task** undertaken in public interest or to exercise of official authority vested in the controller
- 6. Data processing is necessary for the **controller/third party legitimate interests**; except where the data subject's rights and freedoms overrides it, particular if the data subject is a child this does not apply to data processing by public authorities in the performance of their tasks





GDPR: consent

| Must be | Cannot be |
|---|---|
| Given freely, be specific, informed and unambiguous | Assumed from the individual's lack of action/response |
| Obtained by clear affirmative action | Through pre-ticked consent boxes |
| Verifiable and positively opted-in | Obtained by default or by using optout boxes |
| Simple/straightforward to withdraw consent | Part of any terms and conditions of a service |

Consent:

- May not always be required remember there are five other lawful bases permitting the processing of an individual's personal data
- Must be obtained where another lawful basis for data processing is not applicable





GDPR: consent

The Information Commissioner's Office (ICO) recommendations:

- Regularly review and update consent and associated procedures (as necessary)
 - There is no set time limit/expiry date for consent validity
- Keep records of evidence
 - Including the name of individual providing consent, how consent was provided and date/purpose for consent





GDPR: individual rights

- The rights of individuals under the GDPR are similar to those under the DPA; however, there are notable enhancements
- The GDPR provides eight rights for individuals
- Not all of the rights are absolute some rights are only applicable in certain circumstances
- When responding to an individual's request to exercise their individual right, organisations must comply within a definitive time frame





GDPR: individual rights

- 1. The right to be informed
- 2. The right of access
- 3. The right to rectification
- 4. The right to erasure
- 5. The right to restrict processing
- **6.** The right to data portability
- 7. The right to object
- **8.** Rights in relation to **automated** decision making including profiling





GDPR: complying with an individual's request to exercise their right

- Take reasonable steps to verify the identity of the individual
- Comply without undue delay and within specified time frames
- Organisations must provide the information electronically, where possible
- Provide the information free of charge





GDPR: implications

- Organisations are obliged to demonstrate
 compliance the "accountability principle"
- Healthcare sector (incorporating community pharmacy) is at high risk due to the day-today processing of "special categories of personal data"
- Fines can be imposed on organisations who are in breach of GDPR





GDPR: data breaches

- A personal data breach means a breach of security leading to the destruction, loss, alteration, unauthorised disclosure of, or access to personal data
- Requirement for organisations to report certain types of data breaches to the relevant supervisory authority
 - Breaches must be reported within 72 hours
 - Failure to report can result in a fine of up to €10million
 or 2 per cent of the organisation's global turnover
- In some cases, the organisation must contact the affected individual(s)





GDPR: how to prepare

- Raise awareness within your organisation of the forthcoming changes, especially with key decision makers
- Ensure individuals familiarise themselves with, and are aware of, the six lawful bases for processing personal data under the GDPR
- Identify your organisation's lawful basis for processing personal data
- Look into appointment of a DPO





What is the difference between a data controller and data processor?

- A data controller determines how and why personal data is processed. Under the GDPR, the pharmacy organisation is a data controller.
- A data processor carries out processing on behalf of the data controller. All individuals within a pharmacy organisation are acting as data controllers and not data processors.





What is the fine imposed on an organisation if they fail to comply with the GDPR requirements?

The fine is determined by the type of infringement.

The GDPR have outlined the following fine structure:

- A fine up to €10million or 2 per cent of the organisation's global turnover (whichever is higher) for infringements including those relating to the failure to notify the ICO of a data breach and the failure to follow data controller or processor obligations
- A fine of up to €20million or 4 per cent of the organisation's global turnover (whichever is higher) for infringements including those relating to non-compliance of orders from the ICO, failure to follow the basic principles for processing including consent, and individual rights





Can asking a patient/representative to confirm the address verbally when handing out dispensed prescription items be seen as a data breach if others can hear this?

- Yes
- Ensure SOPs consider patient confidentiality, not just to comply with the GDPR, but also to abide by the professional standards set by the GPhC and the Pharmaceutical Society of Northern Ireland (PSNI)
- Consider displaying a patient notice





Is consent always required when processing personal data in a pharmacy?

- Consent is one of the six lawful bases
- Consent must be obtained where no other lawful basis for processing personal data is applicable.
- As there are five other lawful bases to process personal data, consent may not always be required from an individual.





Do all pharmacies need a Data Protection Officer (DPO)?

- Yes.
- All pharmacies process personal health data and under the GDPR, a data protection officer (DPO) is required if an organisation carries out 'large scale processing of special categories of data'.





Part 1: Guidance for Community Pharmacy

Version 1: 25th March 2018









Part 2: Guidance for Community Pharmacy (shorter version)

Version 1: 25th March 2018









Part 3: Workbook for Community Pharmacy

Version 1: 25th March 2018



GDPR and associated legislation Guidance for Community Pharmacy



Contents

| Template A: D ecide who is responsible | 3 |
|--|----|
| Template B: A ction Plan | 4 |
| Template C: Think about and record the personal data you process; | 5 |
| Assure your lawful basis for processing | 5 |
| Template D: P rocess according to data protection principles | 15 |
| Template E: R eview and check with your processors | 16 |
| Template F: Obtain consent if you need to | 18 |
| Template G: T ell people about your processes: the Privacy Notice | 19 |
| Template H: Ensure data security | 22 |
| Template I: Consider personal data breaches | 26 |
| Template K: Think about data subject rights | 32 |
| Template L: Ensure privacy by design and default | 34 |
| Template M: Data protection impact assessment (DPIA) | 3" |





Template C: Think about and record the personal data you process;

Assure your lawful basis for processing

Activity: Receipt, dispensing and submission of NHS paper and electronic prescriptions, including, for example, repeatable prescriptions and related tokens and manual unstructured files of prescriptions.

| DI | Data Cartallar |
|--|---|
| Pharmacy status | Data Controller |
| Data subjects and personal data | Personal data such as patient name, address, contact details, medicines and relevant health data. |
| Purpose | Care of the patient, pharmacy payment and NHS management. |
| Lawful basis for processing personal data | Article $6(1)(e)$ of the GDPR. Necessary for the performance of a task in the public interest. |
| Special category of personal data | Yes, data concerning health (this could include information on a disability). The data may also be another special category of personal data. |
| Basis for processing special category of data | Article 9(2)(h) of the GDPR (including the Data Protection Act). 'The provision of health care or treatment' or 'the management of health care systems or services or social care systems or services' or 'necessary for reasons of public health in the area of public health'. |
| How is data collected? | The patient, or patient's representative, a prescription, healthcare professional, or the SCR record, as appropriate. |
| How is data stored? | Primarily the PMR system, but also e-mail or equivalent (if so, consider security), CD or Specials registers, as relevant and necessary. Manual unstructured files stored in the pharmacy. |
| Howlong is data stored? | According to NHS guidance – the Recommendations for the Retention of Pharmacy Records - prepared by the East of England NHS Senior Pharmacy Managers 2016 in this case the life of the patient plus 10 years. |
| To whom do you provide the data (recipients)? (including processors) | GP practices, NHS Business Services Authority and others in the NHS (e.g. hospitals on admission), and only relevant information to those external to the NHS who negotiate and check our payments; relevant information to NHS organisations and others such as the GPPC for compliance and enforcement purposes. Processors: Click or tap here to enter text. |
| Date confirmed that this applies to your pharmacy | Click or tap here to enter text. |

Template C continued

Activity: Advanced services such as Medicines Use Reviews (MURs), the New Medicine Service (NMS), the NHS Urgent Medicine Supply Advanced Service (NUMAS), Appliance Use Reviews (AUR), Stoma Appliance Customisation (SAC) and the Flu Vaccination Service. Add or remove services as appropriate.

| | I |
|--------------------------|---|
| Pharmacy status | Data Controller |
| Data subjects and | Personal data such as patient name, address, contact details, |
| personal data | medicines and relevant health data. |
| Purpose | Care of the patient, pharmacy payment and NHS management. |
| Lawful basis for | Article 6(1)(e) of the GDPR. |
| processing personal data | Necessary for the performance of a task in the public interest. |
| Special category of | Yes, data concerning health (this could include information on a |
| personal data | disability). The data may also be another special category of personal data. |
| Basis for processing | Article 9(2)(h) of the GDPR (including the Data Protection Act). |
| special category of data | 'The provision of health care or treatment' or 'the management |
| | of health care systems or services or social care systems or |
| | services' or 'necessary for reasons of public health in the area of |
| | public health'. |
| How is data collected? | The patient, or the patient's representative, a prescription, |
| | another healthcare professional, the SCR record, and Advanced |
| | Service form, as appropriate. |
| How is data stored? | Hard copy or electronic (PMR system) records, and hard copy |
| | consent forms as appropriate. |
| How long is data stored? | Click or tap here to enter text. |
| To whom do you provide | GP practices, NHS Business Services Authority and others in the |
| the data (recipients)? | NHS (e.g. hospitals on admission), and only relevant information |
| (including processors) | to those external to the NHS who negotiate and check our |
| | payments; relevant information to NHS organisations and others |
| | such as the GPhC for compliance and enforcement purposes. |
| | Processors: Click or tap here to enter text. |
| Date confirmed that this | Click or tap here to enter text. |
| applies to your pharmacy | |
| | 1 |





GDPR and associated legislation Guidance for Community Pharmacy



Template G: Tell people about your processes: the Privacy Notice

When you collect personal data from a data subject you must provide the data subject with relevant information; the Privacy Notice. This should be available on the pharmacy premises, for example, in a poster or the practice leaflet, and, if appropriate, on the pharmacy website: and you should draw the attention of new customers to the Privacy Notice. Draft shorter and longer forms of notice are as follows.

(name and address) PHARMACY PRIVACY NOTICE

We process your personal data, which includes your name, contact details, prescription medicines and data from other pharmacy and health care services we provide to you (including, for example, pharmacy medicines, medicine use reviews, flu vaccinations and stop smoking services) for the purposes of:

Your care - providing pharmacy services and care to you and, as appropriate, sharing your information with your GP and others in the wider NHS;

Our payments - sharing your information with the NHS Business Services Authority, others in the wider NHS, and sometimes Local Authorities, and only limited information to those external to the NHS who negotiate and check the accuracy of our payments; and,

Management - sharing only limited information with the NHS Business Services Authority and others in the wider NHS, and sometimes Local Authorities; as well as those external to the NHS who ensure we maintain appropriate professional and service standards and that your declarations and ours are accurate.

We hold your information for as long as advised by the NHS. You have a right to a copy of the information we hold about you, generally without charge. You may seek to correct any inaccurate information.

We process your personal data in the performance of a task in the public interest, for the provision of healthcare and treatment and the management of healthcare systems. A pharmacist is responsible for the confidentiality of your information. You may object to us holding your information. You may also lodge a complaint with the Information Commissioner's Office, Wydiffe House, Water Lane, Wilmslow, Cheshire SK9 SAF. Please ask if you want more information. [You may choose to opt out of the NHS using your data for planning and research purposes - please ask for details.]

[Our Data Protection Officer is (name and contact details)]

GDPR and associated legislation Guidance for Community Pharmacy

Our pharmacists and their staff are members of your local healthcare team.

They aim to provide you with the highest quality of healthcare. To do this they need to keep records about you, your health and the care we have provided or plan to provide to you.

We know that you value your privacy and the security of personal information held about you.

Information recorded

As part of providing a professional, safe and efficient service, there is certain information that we record. This includes details of drugs and appliances dispensed against NHS prescriptions as well as significant advice given, and referrals made to other health professionals and any other relevant information.

Information recorded may include:

- · basic details about you, such as address, date of birth, next of kin:
- records of medicines you have been prescribed by your doctor or another

qualified prescriber, and which have been supplied by this pharmacy;

- · details of medicines purchased from the pharmacy without a prescription ("over the counter medicines"):
- · other details and notes about your health and medical treatment:
- information relevant to your continued care from other people who care for you and know you well, such as other health professionals and relatives; and
- · any other services we provide to you, for example, a flu vaccination.

Processing Information

We process your personal data, which includes information from your prescriptions and any other pharmacy and health care services we provide to you (including medicines use reviews, flu vaccinations, stop smoking services etc.) for the purposes of:

appropriate, sharing your information with your GP a to be added] in the wider NHS:

Community Pharmacy GDPR Working Party

Our payments - sharing your information with the NHS Business Services Authority, others in the wider NHS, and sometimes Local Authorities, and only limited information to those external to the NHS who negotiate and check the accuracy of our payments; and,

Management - sharing only limited information with the NHS Business Services Authority and others in the wider NHS, and sometimes Local Authorities: as well as those external to the NHS. who ensure we maintain appropriate professional and service standards and that your declarations and ours are accurate.

We hold your information for as long as advised by the NHS.

We process your personal data in the performance of a task in the public interest for the provision of healthcare and treatment. A pharmacist is responsible for the confidentiality of your information.

Your care - providing pharmacy services and care to . [Additional information/ more detail may need

Page | 20





GDPR and associated legislation Guidance for Community Pharmacy



Template I: Consider personal data breaches (IG Template 11 updated)

| Name of Pharmacy Information Security Incident Management Procedures | | | | |
|--|--|-----------------------------|----------|--|
| Procedures Prepared by: Click or tap here to | Procedures Approved by: Click or tap here to enter text. | | to enter | |
| enter text. Date Prepared: Click or tap here to enter text. | Date Approved: Click or tap here to enter text. | Date Review Takes Place: | | |

Information security incidents are any event that has resulted or could have resulted in the disclosure of confidential information to an unauthorised individual, the integrity of the system or data put at risk or the availability of the information through the system being put at risk. Incidents may include theft, misuse or loss of equipment containing confidential information or other incidents that could lead to authorized access to data.

"Personal data breach" means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

1. Procedures for dealing with various types of Incident

All staff should report any suspicious incidents to Click or tap here to enter text. [extext details e.g. the pharmacist in charge or the IG Lead].

Incidents should always be investigated immediately whilst there is still the possibility of collecting as much evidence as possible. Investigations should normally be co-ordinated between at least Click or tap here to erter text. [enter details e.g. the pharmadst in charge or the IG Lead.]

The following procedures should be followed for particular personal data breaches:

 A) Theft of equipment holding confidential information and unauthorised access to an area with unsecured confidential information:

- . Check the asset register to find out which equipment is missing.
- Investigate whether there has been a legitimate reason for removal of the equipment (such as repair or working away from the usual base).
- If the cause is external inform the police and ask them to investigate.

GDPR and associated legislation Guidance for Community Pharmacy



- If the cause is internal, establish the reason for the theft/ unauthorised access.
- Consider whether there is a future threat to system security and the need to take protective action e.g. change passwords.

B) Access to patient records by an authorised user who has no work requirement to access the record:

- . Interview the person reporting the incident to establish the cause for concern.
- Establish the facts by:
 - Asking the system supplier to conduct an audit on activities by the user concerned.
 - Interviewing the user concerned.
- Establish the reason for unauthorised access.
- Take appropriate disciplinary action and action with the patient(s) where appropriate.

C) Inadequate disposal of confidential material (paper, PC hard drive, disks/tapes):
 This type of incident is likely to be reported by a member of the public, a patient affected, or a member of staff.

- Investigate how the data came to become inappropriately disposed.
- Take appropriate action to prevent further occurrences (e.g. disciplinary, advice/training, contractual).

 Procedure for dealing with complaints about patient confidentiality by a member of the public, patient or member of staff;

- Interview the complainant to establish the reason for the complaint. (Note, any
 complaint by a patient in relation to his NHS services must be investigated and
 handled in accordance with the Terms of Service.)
- Investigate according to the information given by the complainant and take appropriate action.
- . Take appropriate action with the patient(s) as appropriate.
- Categorise and report the incident as described as per 'recording and reporting' requirements.

E) Loss of data in transit e.g. when posting MUR forms to the GP surgery or sending prescriptions to NHS Prescription Services.

- . Investigate, as far as possible what has gone missing and where.
- Take appropriate action to prevent further occurrences (e.g., was the envelope correctly addressed, is there further safeguards that could be introduced).

2. Procedures for recording incidents

A record of all incidents, including near-misses, should be made by completing a copy of the information security incident report form (section 3 below).

GDPR and associated legislation Guidance for Community Pharmacy



Incidents should be classified in the log according to the severity of risk to patients and the pharmacy using the following incident classification system described below. For nearmisses, consider the likely impact if the breach had occurred.

You must document any personal data breaches, as above, even if they are not notified to the ICO. The ICO may inspect your records to verify you are keeping such records.

Incident or personal data breach dassification:

| Insignificant: | Minor: | Moderate: | Major: | Critical: |
|-------------------------|-------------------------|----------------------|--------------------|----------------------|
| (very low risk) | (low risk) | (Likely to result in | (Consider | (Likely to result in |
| | | a risk to the | whether likely to | a high risk to the |
| | | rights and | result in a high | rights and |
| | | freedoms of | risk to the rights | freedoms of |
| | | patients) | and freedoms of | patients) |
| | | | patients) | |
| | | | | |
| Minimal risk - | Minor breach, for | Moderate | Serious breach, | Serious breach in |
| indiscernible effec | | breach, for | for example | terms of volume |
| on patients or the | but files | example | unencrypted | of records, for |
| pharmacy | encrypted, less | unencrypted | dinical records | example over |
| | than 5 patients | dinical records | lost, up to 1,000 | 1,000 patients |
| | affected | lost, up to 20 | patients affected | affected or |
| | | patients affected | or particular | particular |
| | | | sensitivity | sensitivity of |
| | | | | records |
| | | | | |
| Not reported to | Not reported to | Reported to ICO | Reported to ICO | Reported to ICO |
| 100 | 100 | | | |
| | | Communication | Communication | Communication |
| No patients informed | No patients informed | to patients | to patients | to patients likely |
| informed | informed | considered | considered | to patients likely |
| | | Considered | considered | |
| Recorded as a | Recorded as a | Recorded as a | Recorded as a | Recorded as a |
| personal data | personal data | personal data | personal data | personal data |
| breach | breach | breach | breach | breach |
| | | | | |
| | | | | |
| | | | | |





Part 4: FAQs for Community Pharmacy

Version 1: 25th March 2018











General Data Protection Regulation (GDPR)

PHARMACY TEAM TRAINING MANUAL

Disclaimer:

As the information and guidance on the General Data Protection Regulation (GDPR) is constantly being updated, the contents of this training manual and any supporting resources may be subject to change. The information published is, to the best of our knowledge, correct at the time of publication. However, no responsibility will be accepted for any consequences of decisions made using this information.

Welcome

This staff training manual has been produced by the NPA Pharmacy team to enable members of the pharmacy organisation gather an adequate understanding of the upcoming General Data Protection Regulation (GDPR).

The GDPR aims to standardise and simplify data protection rules and strengthen individuals' rights in relation to their personal data.

A fundamental requirement for GDPR implementation is staff awareness. Pharmacy staff must have an understanding about the GDPR, its principles, and the roles, responsibilities and processes of organisations.

How to use this training manual This training manual will help you understand the basis of the new regulation, and more importantly, provide you with information to help ensure compliance with the GDPR.

This training manual has been divided into the four following sections:

- 1. Introduction and background
- 2. Overview of the GDPR
- 3. Changes under the GDPR
- 4. Application of the GDPR

This training is expected to take 90 minutes to complete. It is recommended that you work through

the training manual in the order presented.

Once you have worked through the training manual, you will be given a short multiple choice question (MCQ) assessment for you to complete to demonstrate your understanding of the GDPR.

After completing this training manual and associated MCQ assessment, it is recommended that you seek guidance from your employer, superintendent pharmacist or the person dealing with data protection within the pharmacy, to familiarise yourself with any additional policies and/or procedures which may be applicable to the pharmacy organisation.



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GDPR: Other NPA support

Current NPA support resources available to members

- Brief overview of GDPR
- Consent brief overview
- Individual rights brief overview

Future NPA resources

- Lawful basis of processing brief overview
- Records of processing activities brief overview including data flow template
- Data breaches brief overview
- Training manual for pharmacy support staff

NPA Pharmacy team

 NPA members can contact the Pharmacy team on 01727 891 800 for further information and guidance



