

**General
Pharmaceutical
Council**

In practice: Guidance on consent

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The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales. As part of our role, we set the standards that pharmacy professionals have to meet throughout their careers.

About this guidance

This guidance explains to pharmacy professionals (pharmacists and pharmacy technicians) the importance of consent and their relevant responsibilities. Pharmacy professionals should use their professional judgement in applying this guidance.

Pharmacy professionals should satisfy themselves that all members of the team are familiar with the issues raised within this guidance and understand their own responsibilities in relation to consent.

If a pharmacy professional is not sure about what they should do in a specific situation, they should always ask for advice from their employer, professional indemnity insurance provider, union, professional body or other pharmacy organisation, or get independent legal advice.

This guidance should be read alongside the **standards for pharmacy professionals** which all pharmacy professionals must meet. This guidance covers standard 1 of the standards for pharmacy professionals, which says:

Pharmacy professionals must provide person-centred care



Applying the standard

Every person is an individual with their own values, needs and concerns. Person-centred care is delivered when pharmacy professionals understand what is important to the individual and then adapt the care to meet their needs – making the care of the person their first priority. All pharmacy professionals can demonstrate ‘person-centredness’ – whether or not they provide care directly – by thinking about the impact their decisions have on people.

There are a number of ways to meet this standard, and below are examples of the attitudes and behaviours expected.

People receive safe and effective care when pharmacy professionals:

- obtain consent to provide care and pharmacy services
- involve, support and enable every person when making decisions about their health, care and wellbeing
- listen to the person and understand their needs and what matters to them
- give the person all relevant information in a way they can understand, so they can make informed decisions and choices
- consider the impact of their practice – whether or not they provide care directly
- respect and safeguard the person’s dignity

- recognise and value diversity, and respect cultural differences – making sure that every person is treated fairly whatever their values and beliefs
- recognise their own values and beliefs but do not impose them on other people
- take responsibility for ensuring that person-centred care is not compromised because of personal values and beliefs
- make the best use of the resources available

This guidance is not intended to cover every aspect of consent, and it does not give legal advice. However, it reflects the law in Great Britain at the time of publication.

Pharmacy professionals must make sure that they keep up to date and comply with the law, and with any NHS or employment policies on consent that apply to their particular area of work.

Pharmacy professionals work in many different settings. So how relevant this guidance is to a pharmacy professional, and how consent is obtained, may vary depending on their role and the type of contact they have with people receiving care.

We have a **range of guidance** on our website to help pharmacy professionals apply our standards. In particular, when reading this guidance please also see our ***In practice: Guidance on confidentiality.***

Consent

1. What is consent?

- 1.1. The Oxford English Dictionary defines 'to consent' as 'to express willingness, give permission, agree'.
 - 1.2. People have a basic right to be involved in decisions about their healthcare. Obtaining consent is a fundamental part of respecting a person's rights.
 - 1.3. Obtaining consent is also essential in forming and maintaining effective partnerships between pharmacy professionals and the people receiving care.
 - 1.4. Pharmacy professionals have a professional and legal duty to get a person's consent for the professional services, treatment or care they provide, and for using a person's information.
 - 1.5. Pharmacy professionals must know and comply with the law and the good practice requirements about consent which apply to them in their day-to-day practice.
- pharmacy professional to be dispensed. This is not a lesser form of consent but it is only valid if the person knows and understands what they are consenting to. If a pharmacy professional is not sure whether they have implied consent, they should get explicit consent
- 2.2. Pharmacy professionals must use their professional judgement to decide what type of consent to get. Pharmacy professionals should take into account legal requirements and NHS service requirements, and the policies where they work that may set this out.
 - 2.3. When appropriate, pharmacy professionals should record the fact that the person receiving care has given explicit consent and what they have consented to.
 - 2.4. Consent may be used as a condition for processing a person's information under data protection legislation, including: UK domestic data protection legislation, the **General Data Protection Regulation ((EU) 2016/679) (GDPR)** and the **Human Rights Act 1998 (HRA)**. Consent would be required to allow a person's information to be shared with third parties if there was no other legal basis for doing so. When consent is used as a condition for processing, a person needs to have taken positive action and shown that they agreed to their personal data being processed. This cannot be inferred or taken as

2. Types of consent

- 2.1. There are two types of consent:
 - explicit (or 'express') consent: when a person gives a pharmacy professional specific permission, either spoken or written, to do something
 - implied consent: when a person gives their consent indirectly, for example by bringing their prescription to a

understood from a lack of action – such as a failure to object or to tick an ‘opt-out’ box. Please also see our ***In practice: Guidance on confidentiality*** for more information. For more **guidance on data protection and on consent in the context of GDPR** see the Information Commissioner’s Office (ICO) website.

3. Obtaining consent

- 3.1 For consent to be valid, the person must:
- have the capacity to give consent (see section 4 for an explanation of ‘capacity’)
 - be acting voluntarily – they must not be under any undue pressure from a pharmacy professional or anyone else to make a decision
 - have sufficient, balanced information to allow them to make an informed decision. This includes making sure the person receiving care knows about any material risks involved in the recommended treatment, and about any reasonable alternative treatments. Material risks are those a reasonable person would think are significant in the circumstances, but also those the particular person would find significant. Material risks must be disclosed unless to do so would be seriously detrimental to the person’s health¹. (See also Section 16 – Emergencies, for when it may be allowable not to obtain consent)
- 3.2 The information a pharmacy professional provides to the person must be clear, accurate and presented in a way that the person can understand. For example, pharmacy professionals must consider any disabilities, and any literacy, language or other accessibility barriers.
- 3.3 Pharmacy professionals should not make assumptions about the person’s level of knowledge and they should give them the opportunity to ask questions.
- 3.4 Pharmacy professionals are responsible for making sure that a person has given valid consent. Pharmacy professionals must use their professional judgement to decide whether they themselves should get consent from the person, or whether this
- be capable of using and weighing up the information provided
 - understand the consequences of not giving consent

¹Montgomery v Lanarkshire Health Board. [2015] UKSC 11. www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf

task can properly be delegated. If the pharmacy professional does delegate the task of obtaining consent they must make sure they delegate it to a competent and appropriately trained member of staff.

- 3.5 Getting consent is an ongoing process between a pharmacy professional and the person receiving care. Consent cannot be presumed just because it was given on a previous occasion. Pharmacy professionals must get a person's consent on each occasion that it is needed, for example when there is a change in treatment or service options. Consent must be recorded.
- 3.6 People with capacity are entitled to withdraw their consent at any time. (See section 7 – When a competent adult refuses to give consent.)



Capacity

4. What is capacity?

- 4.1 In England and Wales, under the Mental Capacity Act 2005, a person lacks capacity if, at the time the decision needs to be made, they are unable to make or communicate the decision because of an impairment or disturbance that affects the way their mind or brain works.
- 4.2 In Scotland, under the Adults with Incapacity (Scotland) Act 2000, a person lacks capacity if they cannot act, make decisions or communicate them, or understand or remember their decisions because of a mental disorder or physical inability to communicate in any form.
- 5.3 Pharmacy professionals must not assume that because a person lacks capacity on one occasion, or in relation to one type of service, that they lack capacity to make all decisions.
- 5.4 A person's capacity to consent may be temporarily affected by other factors, for example: fatigue, panic, or the effects of drugs or alcohol. This should not lead to an automatic assumption that the person does not have the capacity to consent. Instead, pharmacy professionals should use their professional judgement to make a decision based on the individual circumstances.

5. Assessing capacity

- 5.1 A pharmacy professional must base an assessment of capacity on the person's ability to make a specific decision at the time it needs to be made. A person receiving care may be capable of making some decisions but not others.
- 5.2 In general, to make an informed decision the person should be able to:
 - understand the information provided
 - remember the information provided
 - use and weigh up the information provided, and
 - communicate their decision to the pharmacy professional (by any means)
- 5.5 Pharmacy professionals must not assume that a person lacks capacity based just upon their age, disability, beliefs, condition or behaviour, or because they make a decision that the pharmacy professional disagrees with.
- 5.6 Pharmacy professionals must take all reasonable steps to help and support people to make their own decisions, or to be as involved as they can be in a decision. They should, for example:
 - time the discussion for when the person's understanding may be better
 - use appropriate types of communication, simple language or visual aids

- get someone else to help with communication, such as a family member, support worker or interpreter
- 5.7 If a pharmacy professional is unsure about a person's capacity, they must get advice from other healthcare professionals or from people involved in their care.
- 5.8 If a pharmacy professional is still unsure, they must get legal advice.
- 5.9 Any advice they get or assessments carried out should be properly recorded, along with the outcome.
- 5.10 Pharmacy professionals can find more guidance on how people should be helped to make their own decisions, and how to assess capacity, in the Codes of Practice that accompany the Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000.



Adults

6. Adults with capacity

6.1 Every adult is presumed to have the capacity to make their own decisions (that is, that they are competent) and to give consent for a service or treatment unless there is enough evidence to suggest otherwise.

7. When a competent adult refuses to give consent

- 7.1 If an adult with capacity makes a voluntary, informed decision to refuse a service or treatment, pharmacy professionals must respect their decision – even when they think that their decision is wrong or may cause the person harm. This does not apply when the law says otherwise, such as when compulsory treatment is authorised by mental health legislation².
- 7.2 Pharmacy professionals should clearly explain the consequences of the decision, but must make sure that they do not pressure the person to accept their advice.
- 7.3 Pharmacy professionals should make a detailed record if a person refuses to give consent. This should include the discussions that have taken place and the advice given.
- 7.4 If a pharmacy professional believes that the person is at risk of serious harm because of their decision to refuse a service or treatment, they must raise this issue with

relevant healthcare or pharmacy colleagues or with people involved in the person's care, and with their own employer (if they have one). They should also consider getting legal advice if necessary.

8. Adults without capacity

- 8.1 If the person is not able to make decisions for themselves, pharmacy professionals must work with people close to the person receiving care and with other members of the healthcare team.
- 8.2 The Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000 set out the criteria and the processes to be followed in making decisions and providing care services when a person lacks the capacity to make some or all decisions for themselves. They also give legal authority to certain people to make decisions on behalf of people receiving care who lack capacity.
- 8.3 If pharmacy professionals believe that a person lacks capacity to make decisions for themselves, they should consult the Codes of Practice that accompany the Mental Capacity Act 2005 or Adults with Incapacity (Scotland) Act (2000). These set out who can make decisions on the person's behalf, in which situations, and how they should go about this.

² Mental Health Act 1983 (as amended by the Mental Health Act 2007), and the Mental Health (Care and Treatment) (Scotland) Act 2003

Young people and children

9. Young people and children

- 9.1 The capacity to consent depends more on the person's ability to understand and consider their decision than on their age.
- 9.2 In this guidance 'a young person' means anyone aged 16 or 17, and 'a child' means anyone aged under 16. However, people gain full legal capacity in relation to medical treatment at a different age in Scotland than in England and Wales.
- 9.3 As with any person receiving care, a young person or child may have the capacity to consent to some services or treatments but not to others. Therefore it is important that pharmacy professionals assess the maturity and understanding of each person individually, and keep in mind the complexity and importance of the decision to be made.
- 9.4 If a person with **parental responsibility** has to give consent, pharmacy professionals may need to get legal advice if:
- they are in any doubt about who has parental responsibility for the person, or
 - those that have parental responsibility cannot agree whether or not to give consent

- 9.5 Young people and children should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own.

10. Young people with capacity

- 10.1 Young people are presumed to have the capacity to make their own decisions and give consent for a service or treatment, unless there is enough evidence to suggest otherwise.
- 10.2 To decide whether a young person has the capacity to consent to a service or treatment, pharmacy professionals should use the same criteria as for adults (see section 5 – Assessing capacity).
- 10.3 Pharmacy professionals should encourage young people to involve their parents in making important decisions. However, pharmacy professionals should respect a competent young person's request for confidentiality.



11. Children with capacity

- 11.1 Children are not presumed to have the capacity to consent. They must demonstrate their competence.
- 11.2 A child can give consent if the pharmacy professional is satisfied that the treatment is in their best interests, and that they have the maturity and ability to fully understand the information given and what they are consenting to. In this case pharmacy professionals do not also need consent from a person with parental responsibility.

12. When competent young people and children refuse to give consent

England and Wales

- 12.1 In some circumstances, the courts can override the refusal of consent of a young person or child. Pharmacy professionals should get legal advice on this issue if needed.
- 12.2 The law is complex when a competent young person or child refuses to give

consent for a treatment or service and someone with parental responsibility wants to override their decision. Pharmacy professionals should get legal advice if they are faced with this situation.

Scotland

- 12.3 When a young person or child has capacity to make a decision, then their decision should be respected. This applies even if the decision differs from the pharmacy professional's view, or from the views of those with parental responsibility.
- 12.4 However, this position has not yet been fully tested in the Scottish courts. Nor has the issue of whether a court can override a young person's or child's decision. Pharmacy professionals should therefore get legal advice if they are faced with this situation.

13. Young people without capacity

England and Wales

- 13.1 A person with parental responsibility for a


young person without capacity can give consent on behalf of that young person to investigations and treatment that are in the young person's best interests.

Scotland

- 13.2 The rights of a person with parental responsibility to make decisions on behalf of a child end when the child reaches the age of 16.
- 13.3 Young people who do not have the capacity to consent should be treated as though they are adults and in line with the Adults with Incapacity (Scotland) Act 2000.

14. Children without capacity

- 14.1 When a child lacks capacity to give consent, any person with parental responsibility for that child, or the court, can give consent on their behalf.



Advance decisions and emergencies

15. Advance decisions

- 15.1 People who understand the implications of their choices can say in advance how they want to be treated if they later suffer loss of mental capacity.
- 15.2 An unambiguous advance refusal for a treatment, procedure or intervention which is voluntarily made by a competent, informed adult is likely to have legal force.
- 15.3 An advance refusal of treatment cannot override the legal authority to give compulsory treatment under the mental health laws.
- 15.4 Any advance decision is superseded by a competent decision by the person concerned, made at the time consent is sought.

England and Wales

- 15.5 Advance decisions are covered by the Mental Capacity Act 2005. For an advance refusal of treatment to be legally valid, it must meet certain criteria set out in the Mental Capacity Act 2005.
- 15.6 If an advance decision does not meet these criteria, it is not legally binding but can still be used in deciding the person's best interests.

- 15.7 Pharmacy professionals must follow an advance decision if it is valid and applicable to current circumstances.

Scotland

- 15.8 The Adults with Incapacity (Scotland) Act 2000 does not specifically cover advance decisions. However, it says that health professionals must take account of the person receiving care's past and present wishes, however they were communicated.
- 15.9 It is likely that pharmacy professionals would be bound by a valid and applicable advance decision. However, there have been no specific cases yet considered by the Scottish courts. If in any doubt, pharmacy professionals should get legal advice.

16. Emergencies

- 16.1 In an emergency, when a person needs urgent treatment, if a pharmacy professional cannot get consent (for example, if the person is unconscious and unable to make a decision) they can provide treatment that is in the person's best interests and is needed to save their life or prevent deterioration in their condition. This applies to children, young people and adults.
- 16.2 There is an exception to 16.1 above if a pharmacy professional knows that there is a valid and applicable advance decision to refuse a particular treatment. For more information pharmacy professionals should see the relevant incapacity legislation and its code of practice, or ask their professional indemnity insurance provider or a legal adviser.

Other sources of information

England and Wales

- Mental Capacity Act 2005
www.legislation.gov.uk/ukpga/2005/9/contents
- Mental Capacity Act Code of Practice
www.gov.uk/government/collections/mental-capacity-act-making-decisions
- National Data Guardian
www.gov.uk/government/organisations/national-data-guardian

Scotland

- Adults with Incapacity (Scotland) Act 2000
www.legislation.gov.uk/asp/2000/4/contents
- Adults with Incapacity (Scotland) Act 2000 - Codes of Practice
www.gov.scot/Topics/Justice/law/awi/010408awiwebpubs/cop

If you have questions or comments about the content of this guidance, please contact our Policy and Standards Team:

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We have also produced guidance on other topics that you may find useful:

www.pharmacyregulation.org/standards/guidance



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