



New medicines in Scotland

– who decides what the NHS can provide?

What is this factsheet about?

This factsheet explains the process that medicines go through before NHS doctors in Scotland can routinely prescribe them.

The person prescribing a medicine must make sure the patient knows how to use it safely. Medicines are usually prescribed by a doctor. In this factsheet, we use the word “doctor” to describe the person prescribing the medicine. The doctor is responsible for choosing the medicine used.

If you have questions about the medicines you have been prescribed or you wish to discuss any part of your NHS treatment, you can ask the doctor in charge of your care.

What happens before a medicine can be prescribed?

- In Scotland, a medicine usually has to have a licence (also known as a marketing authorisation) before it can be prescribed to treat people.
- A licence will only be granted if there is evidence from a clinical trial that the medicine is safe, of good quality, and

worked for those people taking part in the trial. Medicines are usually licensed for use in adults who have a particular illness or condition.

- As well as being licensed, a medicine usually needs to be recommended for use by the NHS in Scotland before it can be prescribed by your doctor.

Who gives a licence to new medicines?

Two agencies license medicines:

- The **Medicines and Healthcare products Regulatory Agency (MHRA)** licenses medicines for use in the UK.
- The **European Medicines Agency (EMA)** licenses medicines for use in all countries of the European Union.

The pharmaceutical company that developed the medicine has to apply to one of these agencies for a licence. Before granting the licence, experts at the agency look at the research to check the medicine's safety and quality, and make sure it works in the way it is supposed to.

Can my doctor prescribe a medicine that doesn't have a licence?

- Unlicensed medicines may not have gone through the full licensing process.
- Normally your doctor will only prescribe a medicine that has a licence.
- However, your doctor can prescribe a medicine that doesn't have a licence if he or she thinks it will benefit you (or your child). But your doctor must let you know that the medicine doesn't have a licence, and get your agreement. And your doctor must take responsibility for the prescription and your (or your child's) care during the time you are taking the medicine.

Can my doctor prescribe any newly licensed medicine?

Usually your doctor will prescribe a licensed medicine only after it has been:

- recommended for use in Scotland by the **Scottish Medicines Consortium**, and

- accepted by your local NHS board for use in your board area.

What is the Scottish Medicines Consortium?

The **Scottish Medicines Consortium (SMC)** advises on the use of new medicines in the NHS in Scotland.

- Before the SMC accepts a medicine for use by the NHS in Scotland, it needs to find out:
 - how effective the medicine is
 - which patients would benefit
 - whether it is as good as or better than medicines the NHS already uses to treat the particular condition
 - what it costs, and
 - whether it is good value for money.

The SMC looks at detailed information from the pharmaceutical company about the medicine. This includes any evidence from clinical trials, and research from countries where the medicine is already being used. The SMC does this as soon as possible after the medicine is licensed.

- If the SMC accepts the medicine for use by the NHS in Scotland, it will publish this on the SMC website (www.scottishmedicines.org.uk). NHS boards and doctors take account of this advice when deciding which medicines should be prescribed.
- Sometimes the SMC accepts more than one medicine for treating a certain condition or disease. Your NHS board can decide which of them your doctor should normally prescribe.
- When NHS boards decide which medicines can be used in their area, they make a list of them. This list is called a 'local formulary'.

Are other organisations involved in approving medicines for use?

- The **National Institute for Health and Clinical Excellence (NICE)** advises the NHS in England and Wales about the use of medical devices and medicines. It does not give official advice to Scotland on medicines.
- However, in Scotland an organisation called **NHS Quality Improvement Scotland (NHS QIS)** considers some of the advice that NICE gives the NHS in England and Wales. If NHS QIS thinks the advice is relevant to patients in Scotland, they will publish it on their website. NHS boards in Scotland must consider this advice when deciding what medicines to recommend.
- The **Scottish Intercollegiate Guidelines Network (SIGN)** is part of NHS QIS. It writes guidelines for health professionals on the best tests and treatments available. Generally SIGN advises on groups of medicines but it does occasionally recommend a specific medicine. The SMC and SIGN work together to make sure the NHS in Scotland receives the same advice on new medicines.

So if the SMC or NHS QIS accepts a medicine for use by the NHS in Scotland, will my doctor prescribe it for me?

- Your doctor will usually only prescribe medicines that have been accepted by your NHS board, and are included in the board's 'local formulary'.
- Even if a medicine is not on the board's 'local formulary', your doctor might still be able to prescribe it if he or she feels it is the best treatment for you.

- If your NHS board agrees that the medicine should be prescribed for you, your NHS board will pay for it.

Can my doctor prescribe a licensed medicine if it hasn't been accepted for use in Scotland?

- If your doctor believes you would benefit from a medicine that has not been accepted by the SMC or NHS QIS, he or she can ask your NHS board if they will provide it.
- Your doctor will need to tell your NHS board how and why you are likely to benefit from the medicine. Your NHS board will consider your doctor's request and make a decision.
- You can ask your NHS board to direct you to a source of help and support through this process.
- If your NHS board decides to provide the medicine, you will not need to pay for it.
- If your NHS board decides not to provide the medicine, your doctor will explain the reasons for this and advise you whether there are grounds for an appeal.

If I cannot get a medicine from the NHS, can I pay privately for it instead?

- Yes, you can pay privately for a medicine that is not available to you from the NHS.
- However, there are likely to be particular reasons why your NHS board has refused to give you the medicine. Your doctor should explain these to you before you decide whether to pay privately for the medicine.

Is it possible to get NHS and private care at the same time?

- If you pay privately for your medicine, you will continue to receive the NHS care you are entitled to, and you will not be charged for it as long as it can be kept separate from your private care.
- Your doctor will tell you if it is not possible to keep your NHS and private care separate. In this case, your doctor will explain your treatment options.
- If you do decide to pay privately for the medicine, you should discuss this with your doctor or someone at your NHS board. They will be able to advise you on how to arrange this (see the section 'Need more information?' for contact details).

What if I'm unhappy about a decision by my NHS board or my doctor?

- If you are unhappy with a decision, you can ask for a second opinion. If you are still unhappy, you can make a complaint. The leaflet '**Making a complaint about the NHS**' explains how to do this. You can get a copy from:
 - GP and dental surgeries, hospitals and other places where you get NHS care
 - the NHS helpline on **0800 22 44 88** (textphone 18001 0800 22 44 88)
 - your local citizens advice bureau (www.cas.org.uk), or
 - www.hris.org.uk

Need more information?

This factsheet gives guidance only. If you want to know more about your right to get a new medicine, please speak to your doctor.

You can also get more information by:

- contacting your local NHS board – each NHS board has someone who can offer you help and advice.
To find contact details for your local NHS board:
 - phone the NHS helpline on **0800 22 44 88**, or
 - look on the internet at www.hris.org.uk
- phoning the NHS helpline on **0800 22 44 88** (textphone 18001 0800 22 44 88) for information on health conditions and services
- contacting your local citizens advice bureau for free confidential and independent advice on many things, including NHS services and your rights. To find your nearest branch, look in your phone book or on Citizens Advice Scotland's website (www.cas.org.uk).

Medicines and Healthcare products Regulatory Agency (MHRA)

10–2 Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Phone **020 7084 2000**
(Mondays to Fridays, 9am to 5pm)
Phone **020 7210 3000**
(outside office hours)
Email info@mhra.gsi.gov.uk
Website www.mhra.gov.uk

Scottish Medicines Consortium (SMC)

Delta House (8th floor)
50 West Nile Street
Glasgow
G1 2NP

Phone **0141 225 6989**

Email qis.smcsecretariat@nhs.net

Website www.scottishmedicines.org.uk

NHS Quality Improvement Scotland (NHS QIS)

Elliott House
8–10 Hillside Crescent
Edinburgh
EH7 5EA

Phone **0131 623 4300**

Email hta.qis@nhs.net

Website www.nhshealthquality.org

National Institute for Health and Clinical Excellence (NICE)

MidCity Place
71 High Holborn
London
WC1V 6NA

Phone **0845 003 7780**

Email nice@nice.org.uk

Website www.nice.org.uk

Scottish Intercollegiate Guidelines Network (SIGN)

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EH7 5EA

Phone **0131 623 4720**

Email sign@sign.ac.uk

Website www.sign.ac.uk

Email ask@hris.org.uk to ask for this information in another language or format.

We have tried our best to make sure this information is correct. However, it is for guidance only so you should not rely on it as a complete statement of the law. If you are thinking about taking legal action, you should contact a solicitor, a citizens advice bureau or another advice agency.

This information is available on the Scottish Government website (www.scotland.gov.uk) and on the Health Rights Information Scotland website (www.hris.org.uk).

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