

## The approval process for your medicine:

### Peer Approved Clinical System Tier Two Process (PACS2)

Information for patients who have been recommended a medicine not routinely available within NHS Scotland

---

This leaflet is to explain the process when your doctor recommends that you should be given a medicine that is not currently routinely available in NHS Scotland. This is called the Peer Approved Clinical System (PACS2) Tier Two process.

#### **What happens next?**

Your doctor will:

- Discuss with you why they think this medicine might help with your treatment
- Advise you on the risks and benefits of the medicine
- Discuss any alternative treatment options that are available to you.

If, following this discussion, you feel that you would like the doctor to apply on your behalf they will complete the request form for this medicine.

#### **Why does this happen?**

The medicine your doctor wants to prescribe for you is not recommended for use or has yet to be considered for use by the NHS in Scotland. The process for considering new medicines is carried out by the Scottish Medicines Consortium (SMC) on behalf of the NHS in Scotland. Reasons why medicines might not be recommended by the SMC can be found at:

[www.scottishmedicines.org.uk/about-us/](http://www.scottishmedicines.org.uk/about-us/)

#### **Who decides if my treatment request is accepted or rejected?**

Your treatment request will be considered by a panel of healthcare professionals, including a senior doctor and a senior pharmacist, within your NHS board.

#### **What does the NHS board consider?**

Your doctor will inform the panel why they believe you should get the medicine. This will include information about what other medicines have been tried or considered for you and why your doctor thinks you will benefit from the medicine. Your doctor will include any other relevant medical details about you. They will also provide details of clinical trials or evidence that support the use of the medicine. Another doctor with experience in your condition will also provide the panel with more information about the request. The panel will consider all of this and other implications for the wider NHS.

#### **Who will put forward my case?**

Your doctor will put forward your case to a panel of healthcare professionals on your behalf. In doing so, they should make sure that you understand the process and the information being submitted on your behalf, and that you agree to them acting for you.

## **How long will it take to hear back?**

Your doctor is responsible for letting the panel know about the level of urgency of the request. The panel will consider the urgency of the request and come to a decision at the earliest opportunity.

## **How will I find out if the request has been successful?**

Your doctor will let you know the panel's decision. If the request is successful, your doctor can now prescribe the medicine for you on the NHS.

## **My doctor's request for the medicine has been turned down. What happens next?**

Your doctor will explain the reasons why the request has been turned down and will discuss any alternative treatment options with you. You and your doctor may also consider whether there are grounds for a review of the decision. If you both believe this to be the case, your doctor can ask for the decision to be reviewed by the National Review Panel.

## **What is the National Review Panel?**

The National Review Panel is independent from your NHS board and is made up of healthcare professionals with relevant expertise and a public partner. Public partners are recruited volunteers who are trained and supported to be panel members, to bring a public perspective to the National Review Panel process.

## **What are the requirements for a review by the National Review Panel?**

Your doctor can submit a request if they think that:

- The NHS board failed to follow the correct process, and/or
- The NHS board reached a decision which was not reasonable on the basis of the information presented.

## **How often does the National Review Panel meet?**

The National Review Panel has the ability to meet every month. If the request is urgent then the panel can meet earlier to ensure you receive an early response.

## **How will I know the outcome of the review?**

Your doctor will let you know the outcome of the National Review Panel and any action the NHS board has to take to make its final decision on the treatment request.

## **Where can I get more information on the National Review Panel?**

More information on the National Review Panel is available on their page of the Healthcare Improvement Scotland website: [www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)

## **Can I complain about the way my treatment request was handled by the NHS board?**

If you are concerned about the way your request was handled, please contact your doctor or local NHS board who will advise you about their complaints procedure.

## **Where can I get support while my treatment request is being considered?**

**NHS board nominated contact(s):**

--

## **Can I complain about the way the review of my treatment request was handled by the National Review Panel?**

If you are concerned about how your request was handled by the National Review Panel, please contact Healthcare Improvement Scotland. Full details of their complaints procedure can be found on their website: [www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)