How new cancer drugs are made available in the NHS

MESOTHELIOMA UK

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Introduction

Researchers are always seeking to improve care for people with cancer. Creating new drugs and finding different ways to use existing ones is an important part of this.

New treatments can offer hope, but first they need to go through a long development and approval process. During this time, researchers make sure the drug not only works, but is also safe to take.

It can take many years and significant resources for a new cancer treatment to be made available to patients.

How new cancer drugs are discovered

The discovery of new cancer drugs can happen in different ways:

Accidental discovery

In the early 1940s, an explosion exposed sailors to poisonous mustard gas. Doctors found that these sailors had low white blood cell counts. They realised that if mustard gas could destroy normal white blood cells, it could also destroy cancerous ones.

Whilst further work was needed to reduce toxicity, they began using it to treat lymphoma, a cancer of the lymphatic system. Accidental discoveries such as this are rare, but nitrogen mustard-derived chemotherapy is still a

cancer treatment used today.

Plants, fungi, and animals

Researchers also study the natural world to find cancer treatments. Paclitaxel (Taxol) treats several types of cancer and was first found in the bark of the Pacific Yew Tree. More recently, the drug Eribulin (Halaven) was developed using a chemical found in primitive animals called sea sponges.

Studying the biology of cancer cells

Looking at how cancer cells develop and grow helps researchers identify new ways to target them and develop new treatments.

For example, the shape of cancer cells can have an impact upon how fast they grow – researchers can then use this information to try and slow down the spread of more aggressive cancers.

Computer simulation

Scientists can use computers to virtually test how a potential cancer treatment would work in real life. Researchers can then make chemical compounds based upon the findings.

Research studies

After drugs are created, researchers test them on human cancer cells in the laboratory. They see if the drugs stop the growth of cancer cells. If this is successful they then test the drug in animals. They

learn how the body uses the new drug. This helps them learn what side effects the drug may cause and what dose of the drug to test in people.

Clinical Trials

The next stage in a drugs development is to test it in clinical trials. There are four phases to testing a drug in clinical trials.

Phase I – tests the drug in humans to try and establish the most effective and safe dose. Usually only 15-30 patients are needed for this phase of trial.

Phase II – Phase II trials further assess safety as well as if a drug works. The drug is often tested among patients with a specific type of cancer. Phase II trials are done in larger groups of patients compared to Phase I trials

Phase III – compare a new drug to the standard-of-care drug. These trials assess the side effects of each drug and which drug works better. Phase III trials enrol 100 or more patients.

Phase IV – trials test new approved drugs. The drug is tested in several hundreds or thousands of patients. This allows for better research on short-lived and long-lasting side effects and safety.

Each trial has its own entry criteria. Healthcare teams should be able to advise on what trials are available and their entry criteria.

Making new drugs available to patients

Once the trials are completed and the drug has achieved a favourable outcome, the next stages are licensing and approval.

Licensing

For a drug to be licensed the manufacturers must prove that it is safe for use, is effective and any side-effects are outweighed by the benefits. The Medicines and Healthcare products Regulatory Agency (MHRA) oversees this process, and is the sole regulator for new medicines in England, Scotland and Wales.

Approval

Once a drug has its licence the next step is for it to be approved for use in the NHS.

This is done by the National Institute for Health and Care Excellence (NICE) or the Scottish Medicines Consortium (SMC). NICE's decisions are also followed in Wales and Northern Ireland.

Both NICE and the SMC assess the clinical effectiveness and cost effectiveness of new treatments and drugs. Cost effectiveness balances cost against the expected health benefits.

Decisions can be based on evidence supplied by health professionals, patients and carers as well

as drug companies.

In Scotland the SMC can make one of three decisions on a medicine:

1. Accepted
2. Accepted with a restriction(s) for example, the medicine can only be recommended in a particular group of patients.
3. Not recommended.

The committee also has the opportunity to accept some medicines on an interim basis subject to ongoing evaluation and reassessment.

In England NICE will choose one of three outcomes:

1. Approval.
   If approved doctors are able to prescribe the new drug to eligible patients.
2. Not approved.
   The new drug has not been approved for use in the NHS.
3. Recommend to the Cancer Drugs Fund.
   This can help patients access promising new treatments.

The Cancer Drugs Fund (CDF) can enable earlier access for patients to drugs that have promising trial results, but don't have enough evidence for NICE to tell if they are cost-effective. Drugs made available on the CDF are available for up to two years to allow more time for evidence to be gathered. After the two years, NICE will then

reconsider if the drug should be routinely commissioned or not.

The CDF is only applicable in England. However, Wales has now introduced the New Treatment Fund which offers access to those drugs approved for use on the CDF and Northern Ireland has also recently announced a similar early access scheme. Scotland does not have a direct equivalent of the CDF. However, all NHS boards in Scotland can consider requests for the use of a medicine for individual patients.

Regardless of where a patient lives, doctors will only recommend a new drug after carefully weighing up the potential risks and benefits for each person.

If you are a mesothelioma patient and would like to find out more about new treatments or clinical trials, ask a member of your clinical team, or contact Mesothelioma UK

For support and information about mesothelioma please contact Mesothelioma UK by emailing info@mesothelioma.uk.com or telephone the freephone information line on 0800 169 2409.

Further information can also be found on the Mesothelioma UK website: www.mesothelioma.uk.com

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