Expanded Access Guide

This document provides information for patients suffering from serious illnesses who wish to gain access to drugs which are still in clinical development or which are unlicensed in their home countries.

What is an Expanded Access Program (EAP)?

These programs, also known as Compassionate Use Programs, distribute potentially life-saving treatments to where there is an unmet medical need. These are treatments that patients cannot access through traditional routes, either because they are not yet licensed anywhere in the world, or because they are only licensed in certain countries.

What is a Clinical Trial?

Before an Investigational New Drug (IND) can receive a license for market use, the drug manufacturer has to prove that the drug is effective and safe for use in humans. To do this the drug must be tested in clinical trials, and the data from the trials must be reviewed by the relevant regulatory body, such as the FDA in the US and EMA in the EU.

For information on clinical trials available to you or your patient, WEP Clinical recommends you visit www.clinicaltrials.gov/. To find out more about how WEP Clinical can help, please visit our website www.wepclinical.com/

How is a clinical trial different from expanded access?

If a patient is suffering from a disease for which there is a new treatment being tested in a clinical trial, the patient has the option to apply for the trial. There are always entrance requirements and not all individuals with the disease will be allowed to enroll.

Those patients who cannot be included in the trial, because they do not meet the inclusion criteria or they live too far from a trial site, can request access to the drug through an EAP (if one is available).

It is important to note that a patient must always be considered for a clinical trial first. Only when the patient cannot enroll in the trial, will the patient be considered for an EAP.

What if the drug is not in a clinical trial and has already been approved, but is not approved in a patient's home country?

Sometimes, a drug can be approved for use in certain countries, but not others. In these cases, a patient in country A, who has exhausted all legal and viable treatment options, can hear about a treatment which is only licensed in country B, C and/or D. This patient's physician can reach out to the manufacturer in these countries and request access to this drug. If the manufacturer agrees to provide the drug, it will be distributed to the physician in country A and provided to the patient through an EAP.

Are there requirements for receiving a drug through expanded access?

To reiterate, only a patient who is not eligible to enroll in a clinical trial, can request access to an investigational new drug through an EAP. Additionally, it is usually required that the patient is either:

- Suffering from a life-threatening or serious illness ***OR***
- At a stage of their serious illness at which they have exhausted all available treatment options and the only option remaining is an investigational treatment or unlicensed drug.

How should a patient/physician submit a request for expanded access?

Patients should not apply for expanded access themselves. A patient's physician, or other healthcare provider, is responsible for submitting a request.

The physician can either contact the drug manufacturer directly to request access through an EAP, or can reach out to us at WEP Clinical, and we can make enquiries on their behalf.

To find out more about WEP Clinical, please visit our website www.wepclinical.com/ ***OR*** ask your Physician to contact us at map@wepclinical.com

Who makes the final decision about whether a patient can receive a drug through expanded access?

It is up to the drug manufacturer to decide whether it will provide its drug to a patient through an EAP. It is important to note that a manufacturer is not necessarily obliged or required to provide its drug to patients outside the clinical trial.

The national regulatory body in a patient's country must also approve the use of the drug once the manufacturer has agreed to provide it.

Why might a drug not be made available by the manufacturer?

The manufacturer may have decided that it does not have the resources to administer an EAP. This may be due to:

- A lack of available staff
- Only having enough drug stock for the trial itself
- No additional budget for the EAP
- A strategic decision not to offer an EAP i.e. wish to focus on the trial and bringing the product to market

For further information

Visit our website at www.wepclinical.com/

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