European Medicines Agency
Evaluation of Medicines for Human Use

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COMPASSIONATE USE FOR CENTRALISED MEDICINAL PRODUCTS

(according to article 83 of regulation (EC) No 726/2004)

What does compassionate use mean?

The European legislation requires that centralised medicinal products are authorised by the European Commission before they are marketed in the Community. Medicinal products that are not authorised yet in Europe, may be given to patients in clinical trials.

Compassionate use programmes are another option, which exists at the level of Member States, to make promising medicinal products available to patients much earlier than their placing on the market.

What is the role of the EMEA and the role of the Member States regarding Compassionate use for centralised products?

The EMEA may provide recommendations to the Member States, on how to administer and use certain products for compassionate use, and may identify the patients that would benefit from the compassionate use programmes using such products.

Compassionate use programmes remain coordinated and implemented by the Member states. The recommendations from the EMEA are complementary to the national legislations and are an option to the Member States that wish to use these recommendations for their patients. EMEA recommendations may also be given to facilitate the harmonisation of compassionate use programmes in Europe.

What are the medicinal products that can be reviewed by the EMEA?

The EMEA can only review medicinal products that are not yet authorised in Europe. These products should be either under investigation in clinical trials, or subject to review by the EMEA for a marketing authorisation. The medicinal products concerned are only those aiming at treating a group of patients suffering from a life threatening disease, and who cannot be treated with a medicinal product already authorised in Europe.

Whom should I speak to, if I wish to enter a compassionate use programme?

If you wish to participate in a compassionate use programme, you should speak to your doctor, who will advise you and explain how compassionate use programmes work in your country. If appropriate, your doctor may speak to the agency that looks after of compassionate use programmes in your country.

How does it work if there is no legal framework for compassionate use in a Member State?

The conduct of compassionate use programmes remain the responsibility and the prerogative of the Member States. The recommendations from the EMEA do not create any legal framework in the Member States.

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What information is published?

On the EMEA website, the name of the medicinal products that have been reviewed by the EMEA will be published. There will also be information on the recommendation given by EMEA: who can take the medicinal products and how to use them.

< **Follow this link for published guideline on compassionate use of medicinal products, pursuant to Article 83 of Regulation (EC) No 726/2004.** >