Principles on

Compassionate Use[1] of Sanofi Investigational Products

Sanofi's mission is to discover and develop safe and effective innovative medicines and vaccines for patients who need them. Clinical trials are a crucial component of this effort, and they help to determine whether the new treatment is safe and effective. Until regulatory authorities make the final decision whether or not to approve the treatment, the treatment remains experimental and is not generally available to patients.

In certain circumstances, however, individual patients who do not qualify for these trials may ask Sanofi for access to the experimental treatment through their physician. Physicians must make the formal request to Sanofi on behalf of the patient.

Sanofi evaluates each request on a case-by-case basis, weighing all of the following criteria:

Patient condition: The patient must have a serious or immediately life-threatening condition with no other treatment options available and does not qualify for an ongoing clinical trial. In the case of vaccines, the patient must be at risk of developing a serious or immediately life-threatening condition of significant public health concern.

Potential benefit: Sanofi has a responsibility to the patient to weigh our understanding of the potential benefit of the experimental product against any risks associated with its use. Sanofi must have sufficient clinical safety and efficacy data about the product to support a favorable benefit/risk ratio for the patient.

Supply: Sanofi must have an adequate supply of experimental product to both provide it to the patient requesting access and to support on-going clinical trials which are critical to getting the new treatment approved.

1 Depending on the circumstances and the country, such access may be called Compassionate Use, Expanded Access, Early Access, Special Access or by other names.

Compliance with laws and regulations: Access to investigational product must be permitted by, and run in accordance with, laws and regulations effective in the country in which the product will be administered. The physician must follow all local and national laws and regulations associated with making a request for such access.

We recognize that patients come to us when they are in need and we will treat every request carefully, fairly and quickly, respecting patient privacy.

In some cases, Sanofi may set up a program designed to provide access to a number of patients. A list of Sanofi's expanded access/compassionate use programs for the US can be found at ClinicalTrials.gov.

Principles on Compassionate Use of Sanofi Investigational Products approved by Sanofi Bioethics Committee (first approval in June 2014 - last review in 2018)