

Roche Global Policy on Continued Access to Investigational Medicinal Product

Executive Summary

Roche is committed to a high standard of quality and ethical conduct in all aspects of conducting clinical trials. As part of this commitment and in accordance with the Declaration of Helsinki, Roche offers patients who participate in Roche-sponsored clinical trials continued access to the investigational medicinal product that they received after trial completion, when appropriate, as described below.

Global Policy

The purpose of this Global Policy is to describe the principles that govern when a patient who participates in a Roche-sponsored clinical trial of an investigational medicinal product shall have continued access to that product after completion of the clinical trial, free of charge, if:

1. The patient has a life threatening or severe medical condition and his/her wellbeing requires continued administration of the investigational medicinal product;
2. There are no appropriate alternative treatments available to the patient; and
3. The patient and his/her doctor comply with and satisfy any legal or regulatory requirements applicable to them.

Exceptions

Roche will not provide continued access to investigational medicinal product as described above if:

1. The investigational medicinal product is commercially marketed in the patient's country and is reasonably accessible to the patient (e.g., is covered by the patient's insurance or wouldn't otherwise create a financial hardship for the patient);
2. Roche has discontinued development of the investigational medicinal product or data suggest that the investigational medicinal product is not effective for the relevant indication;
3. Roche has reasonable safety concerns regarding the investigational medicinal product for the relevant indication; or
4. Provision of investigational medicinal product would not be permitted under the laws and regulations of the patient's country.

Entry into Force

This policy was reviewed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on 18 Sep 2013 and entered into force the same day.