Teva's Policy on Expanded Access Programs

Teva Pharmaceutical Industries Ltd (hereinafter "Teva"), including all its directors, executives, employees and subsidiary and affiliated companies, is committed to applying our expertise and resources to advance access to quality medicine for people around the world. Being a leader in global healthcare means consistently providing innovative and quality medicines to those in need. In line with our mission of improving patient lives, we strive to make medicines widely accessible, while continuing to deliver innovative solutions for unmet needs across our core therapeutic areas. These commitments are consistent with our mission, values and Code of Conduct and form the foundation for Teva's Policy on Expanded Access Programs (hereinafter "the Policy").

Overview

This Policy is intended to help ensure providing access to investigational medicinal products (IMP), including drugs and biologics, is in the best interest of the patient and consistent with Teva's research and pharmacovigilance strategy.

Teva Expanded Access Programs (EAPs) offer a mechanism for access to IMP outside of clinical trials, when deemed appropriate. EAP regulations and terminology vary by country. In some instances, countries use identical terms to describe different approaches. Although not all-encompassing or fully available in every country, for the purposes of this Policy, types of EAPs are described below.

Types of Expanded Access Programs:

1. **Individual patients:** Use of an IMP for treatment of an individual patient. The patient has a serious or life-threatening disease or condition where conventional therapies or treatments have failed and no comparable or satisfactory alternative drug or treatment is available. These programs are typically implemented in response to unsolicited requests from licensed physicians. Examples include, but are not limited to, Named Patient Programs (NPP) (EU), Special Access Programme (Canada), Compassionate Use (EU) and Single Patient Investigational New Drug (US).

2. **Group of patients:** Use of an IMP for treatment of a group of patients. The applicable regulatory agency may request this from Teva when a significant number of individual patient EAP requests are received for the same use of an investigational drug. Teva may also proactively initiate an EAP (Teva-sponsored EAP) for multiple patients, taking into account patient safety and needs, as well as applicable regulatory requirements. Examples include, but are not limited to, After Care (IL), Compassionate Use (EU) and Treatment IND or Treatment Protocol (US).

   Teva-sponsored EAPs are also posted on clinicaltrials.gov.

Eligibility Criteria

Teva considers granting access to an investigational product or biologic only when all of the following criteria are met:

1. The IMP is intended to treat a serious or immediately life-threatening disease or condition.
2. No comparable or satisfactory alternative drug or other therapy is available to treat the particular stage of the disease or condition.

3. If relevant, EAP supply will not interfere with the implementation, continuation or completion of clinical trials conducted by Teva that could support marketing approval or otherwise compromise the potential development of the product.
4. Unless the IMP is indicated for a rare disease or condition, it has **either** been approved by the governing regulatory agency in at least one country **or** Teva is actively pursuing marketing approval with due diligence in at least one country.
5. Available clinical evidence provides a reasonable basis for concluding the potential benefit of the investigation drug or biologic justifies the potential risks **and** the potential risks are not unreasonable in the context of the disease or condition.
6. Clinical trials with the IMP are completed, or if clinical trials are ongoing, the patient **either** does not meet the enrollment criteria for any of those studies **or** they are unable to access a trial center.

Request Process

Information on submitting an EAP request can be found at https://www.tevapharm.com/research_development/clinicaltrials/.

Treating Physician Criteria and Responsibilities

The physician(s) attending to the patient receiving Teva's investigational drug or biologic thorough an EAP must be properly licensed and fully qualified to treat the patient.
As applicable per local regulations, before an investigational drug or biologic is shipped under an EAP, the requesting physicians must agree to the following in writing:

- Notify, or, where required, obtain approval from, the country's regulatory agency for use of the IMP
- Inform the patient of risks associated with the IMP, including whether it has been approved for marketing in any country
- Obtain informed consent from the patient (or the patient's representative) before administering the IMP, in accordance with local laws and regulations, and provide any written patient information (e.g., patient leaflet)
- Report safety information according to Teva's policies and requirements or as dictated by local regulatory authorities. All serious adverse events, irrespective of treatment relatedness, non-serious adverse reactions, pregnancy, special situation reports and protocol defined adverse events (PDAEs), must be reported to Teva or per country-specific laws and regulations
- Maintain the confidentiality of information about the IMP (e.g., IB and dosing information) and only disclose or disseminate such information as necessary
- Store and handle the IMP according to instructions
- Use the IMP only for the EAP and return/destroy any unused amounts as applicable, in compliance with local laws and regulatory requirements

Governance Structure for Expanded Access Programs

Expanded Access Programs are approved and implemented by Teva R&D.