Teva's Policy on Compassionate Use Programs

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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 purpose, values and Code of Conduct and form the foundation for Teva's Policy on Compassionate Use Programs (hereinafter "the Policy").

Overview

This Policy is intended to help ensure that the provision of Teva products for compassionate use is conducted in the best interests of the patients and is consistent with Teva's policies and requirements.
Teva Compassionate Use Programs (CUPs) offer a mechanism to provide access to Teva products to eligible patients outside, of clinical trials or regular marketing access channels as a means to access treatment, when deemed appropriate.
Teva can only consider requests for compassionate use received from a licensed physician(s).
CUP regulations and terminology vary by country. In some instances, countries use identical terms to describe different approaches or use different terms to describe CUPs. Although not all-encompassing or fully available in every country, for the purposes of this Policy, the types of CUPs are described below.

Types of Compassionate Use Programs

1. **Individual patients:** An unsolicited request for a Teva product, submitted by a licensed physician for the treatment of an individual patient.
   Examples include, but are not limited to, Named Patient Programs (NPP) (EU), Compassionate Use (EU) and Individual (or Single) Patients Expanded Access IND Program (EAP) (US).
2. **Group of patients:** A request for use of a Teva product for the treatment of a group of patients. Under this category, Teva may also consider initiating a CUP for multiple patients (e.g., patients who have completed a Teva sponsored study according to the protocol and without safety concerns). In such a cohort program, Teva still requires that unsolicited request(s) from a licensed physician are submitted for approval, and that approval is obtained from the local regulatory authority for its use, as applicable. Examples include, but are not limited to, After Care (IL), Compassionate Use Programs (EU), Expanded Access Program (US) and Treatment IND or Treatment Protocol (US).
   Teva-sponsored CUPs are also posted on ClinicalTrials.gov, when required.

Eligibility Criteria

Teva considers granting access to a Teva product only when all of the following criteria are met:

1. The Teva product 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, and the patient has exhausted all available treatment options.
3. If relevant, CUP 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. When the Teva product is no longer under investigation for that indication, it has either been approved by the governing regulatory agency in at least one country or Teva is actively pursuing marketing approval in at least one country for that indication.

5. Available clinical evidence provides a reasonable basis for concluding: (a) the potential benefit outweighs the potential risks and (b) the potential risks are acceptable in the context of the disease or condition to be treated and the medical history of the recipient patient.

Request Process

CUP requests must be submitted via the CUP Submission Portal, which can be accessed through the Compassionate Use Programs page on the Teva website.

Treating Physician Criteria and Responsibilities

The physician(s) attending to the patient and requesting Teva's product thorough a CUP must be properly licensed and fully qualified to treat the patient.
As applicable per local regulations, before Teva's product is shipped under a CUP, 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 Teva product.
- Inform the patient of risks associated with the Teva product, including whether it has been approved for marketing in any country.
- Obtain informed consent from the patient (or the patient's legal representative) before administering the Teva product, in accordance with local laws and regulations, and provide the patient with any written patient information (e.g., patient leaflet)
- Monitor the patient's condition and report safety information according to Teva's policies and requirements or as dictated by local regulatory authorities. All serious and non-serious adverse events, irrespective of treatment relatedness, pregnancy, special situation reports and protocol defined adverse events of special interest (PDAESIs), must be reported to Teva, and per country-specific laws and regulations. If the local regulations require direct reporting to the health authority, reporting to Pharmacovigilance (PV) will be performed in parallel, according to the regulatory timelines.
- Maintain the confidentiality of information about the Teva product (e.g., Investigator's Brochure (IB) and dosing information) and only disclose or disseminate such information if required by law or regulation and previously authorized by Teva.
- Acknowledge that Teva reserves the right to discontinue the CUP at any time, in accordance with applicable laws and regulations, for reasons including, but not limited to: new safety concerns arising, the Teva product supply is no longer available, the development of Teva Product is stopped and/or Teva Product is available through clinical trials or becomes commercially available, or if a comparable treatment option becomes available.
- The physician is responsible and accountable for the storage, handling and administration of the Teva product according to the applicable instructions.
- The Teva product can be used only for the CUP. The physician is responsible to return/destroy any unused amounts as applicable, in compliance with local laws and regulatory requirements
- Notify Teva if treatment under CUP is discontinued.
- Teva's has a right to audit the CUP (e.g., site audit, documentation audit) to ensure compliance with applicable laws, regulations and guidance or otherwise for safety reasons.

Governance Structure for Compassionate Use Programs

Compassionate Use Programs are approved and implemented by Teva R&D.