Teva's Policy on Managed Access Programs

July 2026

NPS-ALL-NP-01507 March 2025

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, including continuity of care for trial participants.
These commitments are consistent with our purpose, values and Code of Conduct and form the foundation for Teva's Policy on Managed Access Programs (hereinafter "the Policy").

Overview

This Policy is intended to help ensure that the provision of Teva products via managed access programs is conducted in the best interests of the patients and is consistent with Teva's policies, regulatory requirements and ethical standards.
Teva Managed Access Programs (MAPs) is an umbrella term for Teva programs providing access to unapproved products outside clinical trials or regular marketing channels.
The Policy provides a global, principle-based framework while acknowledging that country-specific legislation and guidance take precedence when coordinating, approving, or implementing any local MAP activity.
MAPs are not substitutes for clinical trials and must not be used for promotional purposes. They are managed in accordance with ethical and regulatory standards, only when the patient's unmet need, scientific evidence and regulatory compliance justify access.

Categories of Managed Access Programs

1. **Post-Trial Access (PTA):** Refers to the continued provision of an investigational or unapproved product to patients who have completed a Teva-sponsored clinical trial (CT) and demonstrated clinical benefit or when discontinuation could harm health or well-being.
2. **Compassionate Use Program (CUP):** The umbrella term for Teva programs and regulatory access pathways that provide access to investigational or unapproved products for patients with seriously debilitating, chronic or life-threatening disease or condition, where alternative therapies are not available, have been exhausted or are not clinically appropriate for the patient(s) (i.e. an unmet medical need), or for patients who cannot/have not participated in Teva clinical trial (treatment naïve patients).

   In general, this includes, for any category of MAPs, either individual or cohort of patient access.

Core Criteria for MAPs

Teva considers requests for access to its investigational or approved products under MAPs on a case-by-case basis. Access may be granted only when all of the following criteria are met:

1. **Request Origin and Compliance with Local Regulations**
   Requests must be submitted by a licensed treating physician. Where permitted by applicable local regulations, requests may also be submitted by other qualified healthcare professionals (e.g., advanced practice registered nurses or physician assistants). All requests must be made in accordance with applicable local regulatory requirements and processes.
2. **Clinical Trial Considerations**
   For products that are still under clinical investigation:

- The patient is not eligible for, or cannot access, an ongoing clinical trial (e.g., due to exclusion criteria, geographic limitations, or trial availability).
- Providing access through the MAP must not interfere with the initiation, conduct, or completion of any ongoing or planned clinical trials.
- Where a Long-Term Extension (LTE) or Open-Label Extension (OLE) study is not feasible, planned, or required by local regulations, a Post-Trial Access (PTA) program should be established to ensure continuity of care for patients who participated in clinical trials and continue to benefit from the investigational product. Such planning should be undertaken proactively, taking into account product development timelines and anticipated future availability.

3. **Regulatory Status of the Product**
   - If the product is no longer under investigation for the intended indication:
     - The product has been approved by at least one regulatory authority for that relevant indication; or
     - Where the product has not yet been approved for that indication anywhere in the world, Teva is actively pursuing marketing authorization in at least one country.
4. **Benefit–Risk Assessment**
   The available clinical evidence must support a reasonable expectation that:
   - The potential benefit to the patient outweighs the potential risks; and
   - The potential risks are acceptable in the context of the patient's condition and medical history.
5. **Regulatory and Ethical Requirements**
   All applicable local regulatory, legal, and ethical requirements must be met, including:
   - Obtaining informed consent from the patient or their legal representative;
   - Compliance with all relevant local expanded access or compassionate use regulations;
   - Meeting all applicable transparency and reporting obligations in accordance with regional and local requirements;
   - Processing personal data and medical information in accordance with applicable privacy and data protection laws.
6. **Required Approvals**
   Where required by applicable law or regulation:
   - Authorization from the relevant Health Authority (HA) or Ministry of Health (MoH) must be obtained; and
   - Review and/or approval by an Ethics Committee (EC) or Institutional Review Board (IRB) must be secured.
7. **Non-Promotional Nature of MAPs**
   MAPs are strictly non-commercial and non-promotional in nature. No marketing or promotional activities are permitted in connection with MAPs. Access to, or participation in, a MAP is not, and must not be treated as, contingent upon any past, present or future decision to prescribe, purchase, or recommend any Teva product, or to refer, enrol, or retain a patient in a Teva-sponsored clinical trial.
8. **Program Duration and Termination**
   For ongoing programs, a clear plan must be established outlining the conditions and processes for

program continuation and termination. These may include, but are not limited to:

- Regulatory approval or commercial availability of the product
- Availability of an alternative, clinically appropriate therapy
- Product supply considerations
- Changes to the product's risk–benefit profile

Note: Meeting the stated criteria does not automatically guarantee access to Teva products via MAPs. Teva retains sole discretion to grant or deny access.

Request Process

MAP requests must be submitted via the dedicated Submission Portal, which can be accessed through the Managed Access Programs (former Compassionate Use Programs) page on the Teva website, following fully the given instructions for portal access and request submission.

Treating Physician Criteria and Responsibilities

As applicable per local regulations, before Teva's product is shipped under a MAP, the requesting physicians and/or healthcare professionals 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 authorized by Teva. Where disclosure is required by law or regulation, prior notice must be provided to Teva to the extent legally permissible.

• Acknowledge that Teva reserves the right to discontinue the MAP at any time, in accordance with applicable laws and regulations and subject to appropriate patient safety considerations and any required transition planning, 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/site healthcare professional 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 MAP. The physician/site healthcare professional is responsible to return/destroy any unused amounts as applicable, in compliance with local laws and regulatory

requirements
• Notify Teva if treatment under MAP is discontinued.
• Teva's has a right to audit the MAP (e.g., site audit, documentation audit) to ensure compliance with applicable laws, regulations and guidance or otherwise for safety reasons.

Governance Structure for Managed Access Programs

MAPs are approved and implemented by Teva R&D.