EngageMate (Healthcare Community Interactions System) Policy & Procedure

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Purpose

This Policy establishes minimum standards for using EngageMate, Teva's Healthcare Community Interactions System ("EngageMate"). EngageMate manages the submission, review, approval, documentation, and Close-Out of an Activity involving interactions with Service Providers from the Healthcare Community. EngageMate and this Policy support Teva's personnel in complying with Applicable Laws and Codes and other policies and procedures when conducting these activities.



Scope

In Scope:

- Creating an Activity
- Nominating a Service Provider
- Calculating Fair Market Value
- Reviewing and approving a Service Provider or Activity
- Documenting Proof of Service
- Closing out the Activity

Application

All Teva Organizations Worldwide must comply with this Policy when engaging Service Providers from the Healthcare Community.

Teva personnel should promptly report any known or suspected violation of this Policy & Procedure or Applicable Laws and Codes in accordance with Teva's Code of Conduct. Any Teva personnel receiving a report of noncompliance alleging corruption, fraud, or financial misconduct, should promptly forward complete details to Teva's Office of Business Integrity (OBI). Teva will not tolerate retaliation against anyone making a good faith report. Any breach of this Policy & Procedure, including failure to report actual or potential violations, may result in disciplinary measures, up to and including termination of employment.

Guiding Principles

- Teva complies with all Applicable Laws and Codes and avoids situations that are contrary to Teva's values or that may damage Teva's reputation.
- Teva complies with our Code of Conduct, Prevention of Corruption Policy, and local policies and processes.
- Teva contracts and pays Service Providers, including Healthcare Professionals (HCPs),
 Healthcare Organizations (HCOs), and other Members of the Healthcare Community based
 on bona fide bargaining between well-informed parties in arm's-length transactions for
 the goods or services to be provided.
- Teva complies with the reporting of payments and Transfers of Value provided to recipients as required under relevant Transparency Reporting requirements and in accordance with Applicable Laws and Codes.



General Procedural Standards

- a. EngageMate manages the process where Submitters (sometimes on behalf of Project Originators) submit Activities involving Service Providers for approval by Reviewers.
 - For purposes of this Policy, Service Providers include:
 - Healthcare Professionals (HCPs)
 - Healthcare Organizations (HCOs)
 - Patients/Caregivers
 - Patient Organizations
 - Third Party Representatives (TPR)
 - Government Officials
 - Government Entities
 - Non-Government Organizations
 - Influencers
 - Payers
- b. Use EngageMate to complete all requirements and actions in this Policy for submitting, reviewing, documenting, and closing out in-scope Activities defined in the next section.
- c. Prior to engaging in Activities, all Submitters, Project Originators, and Reviewers must review and understand the controls and guidelines in Teva's Code of Conduct, Global Prevention of Corruption Policy, applicable functional, regional or local policies/SOPs, and any other company standards, including travel requirements, meal and gift limits, due diligence procedures, and donations procedures.
- d. Activities submitted in EngageMate have three key status designations:
 - Approved: Submitted Activity was reviewed and applicable submission requirements were met. An Activity should begin only after receiving Approved status, and will move to Close-out status the day after the Activity starts. Close-out status indicates the Activity started, and allows Submitters to enter any expense associated with the Activity.
 - Rejected, Submitted Activity was reviewed; but not approved by Reviewers.
 <u>Do not conduct</u> Activities with a status of Rejected, and
 - Request More Information. The Submitted Activity was reviewed; but requires additional
 information or documentation before Reviewer(s) can approve. The Submitter is
 responsible for obtaining and uploading the requested information. An Activity in this
 status cannot start until it obtains full approval and the status changes to Approved.
- e. Submitters and Project Originators are responsible for ensuring:
 - Information and supporting documentation for an Approved Activity is complete, accurate and compliant with Teva's policies, SOPs, standards, Applicable Laws and Codes and Transparency Reporting requirements, and
 - Signed Service Provider contracts (in Close-Out) are consistent with approved contract in EngageMate.
- f. To ensure Activities are appropriately closed in the system, user accounts of employees no longer employed at Teva will be delegated to the employee's manager, unless otherwise requested by the manager. Delegations are assigned by person, not by Activity.



- g. Retain all information and documentation according to Teva's Record & Information Management process.
- h. Contact your Local Compliance & Ethics Officer (LCO) for guidance on:
 - Activities that are not defined in the next section and local submission requirements.
 - Changes to an Approved Activity. For example, changes to business purpose, anticipated outcomes, number of Service Providers, donation or grant recipients, budget, scope, etc.
 Changes may require re-approval or additional documentation.
- Contact Teva's Global Compliance & Ethics Program Office with technical or system-use questions.

Activities Requiring Review

- a. The following Activities are available in EngageMate:
 - Advisory Board/Expert Meeting
 - Donations HCO/GO
 - Donations Non-HCO and Non-GO
 - Corporate Membership
 - Educational Grant/Scholarship
 - Educational Sponsorship
 - Fee For Service
 - Hospitality
 - Items/Gifts
 - Market Research
 - Patient Support
 - Post Marketing Study/Collaborative Research
 - Research Grant
 - Scientific/Investigator Meeting
 - Site Visit
 - Speaker Bureau
 - Speaker Program
 - Speaker Training
 - Sponsorship of Third-Party Activity
 - TPR Engagement

Creating and Submitting an Activity

- a. Submit Activities in EngageMate before the Activity occurs and ensure sufficient time for all required reviews and approvals.
- b. Ensure that the proposed Activity has a legitimate business purpose and complies with Teva's policies, SOPs, standards, Applicable Laws and Codes, and Transparency Reporting requirements.
- c. Upload Activity documentation required by functional or local SOPs and/or as directed by Global Compliance & Ethics during Activity creation.



Nominating a Service Provider

- a. Nominate Service Provider(s) for review and approval if required for the proposed Activity.
- b. Create new records only for Service Provider(s) not already in the Customer Master.
- c. Previously assigned Fair Market Value (FMV) Tiers cannot be changed by creating a new Service Provider record in the Customer Master. For changes to a Service Provider's Tier, request an FMV Modification. Appropriate Reviewers will assess the request.
- d. Upload supporting documentation required for nominating a Service Provider(s) and/or FMV Modification, following functional or local SOPs and/or as directed by Global Compliance & Ethics.

Calculating Fair Market Value (FMV)

- a. Use pre-established FMV rates, based on Tier, for compensation to Service Provider(s).
- b. Submit FMV exceptions using the FMV Modification functionality.
- c. If needed, request a FMV Modification and appropriate Reviewers will assess and provide approval, if applicable. FMV Modifications can be requested for the following reasons:
 - Preparation Time (Prep Time)
 - o Travel Time
 - Tier Change
 - o One-Time Rate Change
 - Permanent Rate Change
- d. Ensure all applicable documentation (according to functional or local SOPs) has been completed and uploaded in EngageMate for the Approved Activity.
- e. Ensure total compensation to a Service Provider reflects actual preparation, service, or Travel Time; do not inflate time to increase total compensation.
- f. For Cross-Border Activities, follow the standards of the Service Provider's Country of Residence for Preparation Time, Travel Time and FMV unless otherwise required by local laws or regulations of the host country.

Reviewing Service Provider(s) and Activity

- a. The Activity's risk level and Estimated Budget Amount are key elements that determine the review process and required approvals. These elements, including a budget threshold which triggers a Level 2 Activity review, were taken into consideration in the determination of the approval workflow.
 - Lower risk activities, defined as Level 1 Activities, require a thorough review and approval by the Project Originator (if applicable) and by the Designated Reviewer.
 The Designated Reviewer is typically the Submitter's manager. Designated Reviewers are not Compliance Reviewers.



- Higher risk activities, defined as Level 2, also require a thorough review by the Project Originator and Designated Reviewer, as well as other applicable Reviewers (e.g., Functional Reviewers or Compliance Reviewers).
- When necessary, Compliance Reviewers can add up to three (3) Additional Reviewers to a Level 2 Activity review.
- b. Only Global Compliance & Ethics can request changes or updates to any aspect of review process requirements. For example, changing review levels from Level 2 to Level 1, or changing required Reviewers for a Level 2 review group.
- c. Reviewers are responsible for confirming that the submission:
 - o Includes all required and accurate information and documentation,
 - States Teva's business need, strategic approach, reflecting a legitimate business purpose, and
 - Complies with Teva's policies, SOPs, Standards, Applicable Laws and Codes, as well as local Transparency Reporting requirements.
- d. If the submission fulfills the requirements above, Reviewers may approve the Activity in EngageMate.
- e. Submitters and/or Project Originators may start an Activity only after obtaining a complete approval in EngageMate.
- f. Submitters are responsible for Canceling or Closing-out Activities that have occurred or will not occur.
- g. Designated Reviewers only review activities that fall under their responsibility and cannot serve as Reviewers for Activities where they are the Submitter or Project Originator.
- h. EngageMate's Cross-Border functionality automatically routes Service Providers for review to the relevant LCO of the Service Provider's country of residence.

Documenting Proof of Service and Close-out of an Activity

- a. Complete all Close-Out activities according to the requirements and timelines in functional or local SOPs and/or as directed by Global Compliance & Ethics and applicable Transparency Reporting requirements.
- b. Submitters must confirm during Close-Out whether each nominated Service Provider conducted the contracted service for the Activity.
- c. Enter actual Spend into EngageMate for Activities with Service Providers from countries with Transparency Reporting requirements, including Spend related to Cross-Border Activities (that is, when a Service Provider is from a different country than the Submitter or Project Originator).
- d. Include detailed Spend data for each Service Provider and all supporting documentation, such as signed contracts, invoices, and proof of payment.
- e. Retain Proof of Service and other records (for example: photographs, project reports, acknowledgments from beneficiaries/ recipients, etc.) as required by accounting, finance, and functional or local compliance SOPs and/or as directed by Global Compliance & Ethics.



- f. Upload required documentation into EngageMate as required by functional or local SOPs and/or as directed by Global Compliance & Ethics during the Activity's Close-Out.
- g. Project Originators identified during the Activity submission must certify and complete the final step in the Activity's Close-Out.

Exceptions

The Global Chief Compliance Officer has the authority to approve or deny exceptions to this Policy, which the Global Compliance & Ethics Program Office will document.

Resources

Name of Resource	Location of Resource
Teva's Code of Conduct	MyTeva intranet (<u>link</u>)
Global Prevention of Corruption Policy	MyTeva intranet (<u>link</u>)
Teva's Global Compliance & Ethics Program Office	GC&E Operations Mailbox: ComplianceOperations@tevapharm.com

Glossary

- **Activity** An activity that is required to be submitted in EngageMate and must also be reviewed and approved before execution of the activity occurs.
- Anything of Value Anything that has monetary value or would constitute an advantage, financial or otherwise, to the recipient, for example: cash or a cash equivalent, services, offers of employment, fee-for-service contracts, charitable donations, political contributions, travel and/or entertainment expenses, meals, drug samples, gifts, conference and registration fees, and discounts not readily available to the public
- Applicable Laws and Codes The international, regional, national, and local laws, regulations, competent authorities' decisions and guidelines, and industry codes governing the activity or interactions, which may include, those of the country where the Teva entity responsible for the



- activity is located, where the activity or interaction takes place, and/or where the Healthcare Professional (HCP) practices their profession.
- Approved Activity status provided when a Submitted Activity was reviewed, and applicable submission requirements were met. An Activity should begin only after receiving Approved status and will move to Close-Out status the day after the Activity starts. Close-Out status indicates the Activity started and allows Submitters to enter any expense associated with the Activity.
- Cancelled Activity status provided after an Activity has been created but the event was not
 executed.
- Close-out Activity status indicating the Activity has started. Activities in this status are
 editable, allowing Submitter's to document expenses associated with the Activity (if
 applicable). Activities move from Approved status to Close-out status one day after the
 Activity's start date.
- Country Financially Responsible The country responsible for the Service Provider payment and/or activity-related expenses. The Submitter selects the country when creating the activity.
- Cross Border Activities Activities which include a nominated Service Provider that practices
 in a country different than the Country Financially Responsible selected in the submission for
 the activity.
- **Estimated Budget Amount** The estimated amount of expenses required to execute the activity. Expenses can include to consulting payments, meals, support for patient organization activities, lodging, value of donations, other fees, etc.
- Fair Market Value (FMV) The value that would be paid as a result of bona fide bargaining between well-informed parties in arm's-length transactions for the goods or services to be provided. The value shall consider the nature or quality of the goods or services to be provided, the qualifications of the provider, the geographic location where goods or services are to be provided, the nature of the market for the goods or services to be provided, and the prevailing rates for similar goods or services.
- FMV Modification The action of requesting a value (usually an hourly payment rate or total hours which are used to determine the Service Providers payment) that exceeds the standard value allowed.
 - Preparation Time ("Prep Time") The amount of time allotted for the nominated
 Service Provider to prepare for the activity.
 - Travel Time The amount of time allotted for the nominated Service Provider to travel to an activity.
 - Tier Change When the nominated Service Provider has an update to their CV and now has additional criteria to consider for their Tier.
 - One-Time Rate Change To pay the nominated Service Provider one time above the maximum amount allowed for the Tier assigned.
 - Permanent Rate Change To pay the nominated Service Provider for this activity
 above the maximum amount allowed for the Tier assigned and to indicate the amount
 approved as their top rate to pay.



Government Entity –

- Federal, national, state, provincial, local, or municipal body or any department, agency, or subdivision thereof
- Government-owned or -controlled enterprise or organization
- o Public international organization (e.g., UN, World Bank, EU, WTO, NATO)
- o Political organization or office; or
- Entity that is considered a government body under applicable local law.

Government Official (GO) –

- Elected, appointed, or career official or employee of a federal, national, state, provincial, local, or municipal government or any department, agency, or subdivision thereof
- Officer or employee of a government-owned or –controlled enterprise or organization (e.g., a Healthcare Professional (HCP) practicing at a government-owned or –controlled hospital or clinic)
- Officer or employee of a public international organization (e.g., UN, World Bank, EU, WTO, NATO)
- o individual acting for or representing a government or any of the organizations referred to above, even if they may not be an employee of such government or organization
- o individual who is considered to be a GO under applicable local law
- Candidate for political office or official of a political party; or
- o Family member of any of the GOs described above.
- Healthcare Community Healthcare Professionals (HCPs), Teva's Customers, Healthcare
 Organizations (HCOs), HCP associations, payers, non-HCP researchers related to Teva's
 research and development projects, universities involved in research or education related to
 medical or pharmaceutical science, government institutions providing services to Teva,
 patients' associations, patients' advocacy groups, and journalists, collectively.
- **Healthcare Organization (HCO)** An entity providing healthcare services including hospitals, clinics, pharmacies, and group medical practices.
- Healthcare Professional (HCP) A member of the medical, dental, pharmacy, and nursing professions and any other individuals who, in the course of their professional activity, are qualified or permitted to prescribe, supply, administer, purchase, recommend, reimburse, pay for, or acquire a medicine, or influence or authorize any of the foregoing. The term also includes health service managers and administrative or clinical support staff who provide support to HCPs, as well as any employees of any entity that is owned by or comprised of HCPs. Examples of HCPS include physicians, nurses, medical assistants, pharmacists, paramedics, product formulary committee members, clinical investigators, and public and private hospital employees.
- **Level 1 Activity** An activity requiring reviews from Projector Originator (if applicable) and the Designated Reviewer.
- Level 2 Activity An activity requiring the full review group to review the activity.



- Local Compliance & Ethics Officer (LCO) Designated individuals throughout Teva who
 provide the on-the-ground support for all compliance program elements, in countries where
 Teva has Commercial, TGO or R&D organizations.
- Proof of Service Evidence proving a Service Provider completed the contracted services, or evidence proving an activity occurred as described in the activity submission. Examples of Proof of Service documentation can include sign in sheets, grant reconciliation, Teva mentioned as sponsor in an event program/brochure, etc.
- **Project Originator** The owner of the activity (i.e., Business Sponsor), responsible for all aspects of the submission, not just the data entry of the submission.
 - For example: An Administrative Assistant, creating an Activity submission on behalf of a Product Manager is a Submitter, while the Product Manager is the Project Originator,.
 - Project Originators are required to certify the activity's alignment to Teva policy and procedures before an activity can be closed out.
- Record & Information Management Teva's process ensuring all official business records are retained for the appropriate legally defined retention period, per Teva's Global Records Retention Schedules.
- Rejected Activity status provided when a Submitted Activity was reviewed, and the Reviewer
 deems the submitted activity does not meet Teva's strategic business approach and thus must
 not be executed. Employees must not conduct Activities with this status.
- Request More Information Activity status provided when a Submitted Activity was reviewed but the Reviewer(s) requires additional information, clarification, or documentation before they can approve. The Submitter is responsible for obtaining and uploading the requested information. An Activity in this status cannot start until it obtains full approval and the status changes to Approved.
- Reviewer System users whose main responsibilities include reviewing and rendering a decision for an activity and/or nominated Service Providers.
 - Designated Reviewer An individual identified by the Submitter as the responsible reviewer of an activity. Designated Reviewers are typically the Submitter or Project Originator's manager; however, the system allows Submitters to select a Designated Reviewer.
 - Functional Reviewer An individual, who is part of the Level 2 review group and automatically assigned by the system.
 - Additional Reviewer A Reviewer, identified by the LCO, and manually added to review an activity.
- Service Provider (SP) An entity or individual that engages with Teva and whose interactions with Teva requires approval in a designated system per relevant global, functional, or local policy or SOP.
 - For purposes of this Policy, this definition only applies to Service Providers in the EngageMate system, which are classified as:
 - Healthcare Professional (HCP)
 - Healthcare Organization (HCO)



- Patient/Caregiver
- Patient Organization
- Third Party Representative (TPR)
- Government Official
- Government Entity
- Non-Government Organization
- Influencer
- Payer
- **Service Provider's Country of Residence** The country where the Service Provider resides or has its place of business.
- **Spend** The monetary value of an expense provided to either a nominated Service Provider or an attendee at the approved activity.
- Submitter System users who create activity submissions for the review of system Reviewers, and who are also responsible for providing complete Close-out data and documentation for activities. Submitters (not submitting an Activity on behalf of a Project Originator) are also consider the Business Sponsor of the Activity.
- **Teva Organizations Worldwide** Teva Pharmaceutical Industries Ltd. and its subsidiaries and affiliates in which Teva holds, directly or indirectly, 50% or more of outstanding equity interest, voting power, or rights to appoint at least one of the directors and managers.
- Third Party Representative (TPR) -
 - A Third Party whom Teva provides or sells goods and who further provides or sells these goods, directly or by an intermediary, to Government Officials (GOs), Government Entities, or Healthcare Organizations (HCOs); or
 - A Third Party engaged and/or paid by Teva that may, with reasonable foreseeability, act on behalf of or represent Teva, directly or by an intermediary, in front of GOs, Government Entities, HCOs, or Healthcare Professionals (HCPs).
- Tier A value assigned to an individual HCP, based on the evaluation of an HCP's background and expertise level, to determine the Fair Market Value rate of compensation for their services.
- Transfer of Value The provision of Anything of Value from Teva to a Service Provider.
 Transfers of Value can be made directly or indirectly to the Service Provider and can be cash or cash equivalent.
- Transparency Reporting Requirements and procedures for the collection of relevant transfers of value (spend) provided to Members of the Healthcare Community, including HCPs and HCOs, for the purpose of complying with transparency reporting laws and codes.

