



SEALED

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA

Plaintiff,

vs.

- (1) PURDUE PHARMA L.P.;
- (2) PURDUE PHARMA, INC.;
- (3) THE PURDUE FREDERICK COMPANY,
- (4) TEVA PHARMACEUTICALS USA, INC.;
- (5) CEPHALON, INC.;
- (6) JOHNSON & JOHNSON;
- (7) JANSSEN PHARMACEUTICALS, INC.,
- (8) ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS;
- (9) JANSSEN PHARMACEUTICA, INC.,
n/k/a JANSSEN PHARMACEUTICALS, INC.;
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,
f/k/a ACTAVIS, INC., f/k/a WATSON
PHARMACEUTICALS, INC.;
- (11) WATSON LABORATORIES, INC.;
- (12) ACTAVIS LLC; and
- (13) ACTAVIS PHARMA, INC.,
f/k/a WATSON PHARMA, INC.,

Defendants.

STATE OF OKLAHOMA
CLEVELAND COUNTY J.S.S.
FILED In The Clerk
Office of the Court Clerk
MAY 02 2019

For Judge Balkman's
Consideration

In the office of the
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

SEALED

DEFENDANTS TEVA PHARMACEUTICALS USA, INC.,
CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC,
AND ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.'S
MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT

EXHIBIT 53 FILED UNDER SEAL

EXHIBIT 53

73071		TITLE Independent Medical Education Grants
US POLICY - 205	OWNER U.S. Medical Affairs	DATE August, 2013 SUPERSEDES July, 2012

1 PURPOSE

Teva is committed to supporting innovative, high-quality initiatives that provide healthcare professionals with evidence-based, clinically-relevant, performance-based education, in order to advance healthcare practice and improve patient outcomes.

Teva is also committed to supporting education for patients and caregivers relating to healthcare issues, advances in medical care, and/or improvement in patient outcomes.

This document outlines the submission, review and approval processes for supporting independent medical education (IME) grants, non-accredited grants, and patient/caregiver education grants, as well as, in addition to the reconciliation and evaluation of supported activities.

2 SCOPE

The policy applies to: ~~all Teva U.S. employees.~~

-U.S. Medical Education

-U.S. Legal

-U.S. Compliance

-U.S. Medical Affairs

-U.S. Sales/Marketing

3 POLICY DETAILS

Teva supports independent medical education activities for health care professionals (HCPs) that comply with:

- o FDA's Guidance for Industry on "Industry-Supported Scientific and Educational Activities" (Nov. 1997)
- o American Medical Association (AMA) "Guidelines on Gifts to Physicians" and "Ethical Opinion on Continuing Medical Education"
- o PhRMA Code on Interactions with Healthcare Professionals (2009)
- o Applicable standards of the Accreditation Council for Continuing Medical Education (ACCME) and all relevant accrediting bodies, including the "Standards for Commercial Support of Continuing Medical Education" and the "Essential Areas, Elements and Decision-Making Criteria"

Independent medical education activities must remain independent from Teva and no Teva personnel or Teva agent may control any aspect of an independent education activity.

All grant support is independent of considerations of product promotion or sales. There must not be any real or perceived *quid pro quo* to purchase, prescribe or provide favorable formulary status of any Teva product (i.e., it should not be perceived that a grant is being offered or solicited in exchange for a business favor even when it is not). No grant determination should be associated with perceived or proposed impact on sales or marketing. "Return on Investment"

(ROI) or similar analyses should not be conducted on any independent medical education activity.

3.1 IME Grant Criteria

In order to be considered for grant support, all proposed independent medical education activities must:

- o Meet a legitimate health education or medical education objective
- o Serve a broad audience of healthcare professionals or healthcare organizations (Meaning the activity is not intended to help one singular organization or business (i.e. Physician Practice, Health Insurance companies, Internal Education for an Organization))
- o Be developed and conducted independently of Teva
- o Be objective, balanced, and scientifically rigorous and accurate

Grant support must be used in its entirety in support of the proposed educational activity or activities. (See Financial Reconciliation)

3.1.1 Types of Grants

Independent U.S. Medical Education

The types of programs/activities for which Teva may provide grant funding fall into the following main categories:

- 1) Financial support provided to fund independent accredited and non-accredited-educational initiatives (CME) designed to (1) communicate healthcare information consistent with Teva's educational objectives to healthcare professionals, and (2) advance the practice of medicine, and (3) improve patient outcomes. Examples may include: live symposium at medical conferences, fellowships, web activities programs and mobile applications, and print materials, enduring material, grand rounds and fellowships.
- 2) Financial support provided to fund independent educational initiatives designed to (1) communicate healthcare information consistent with Teva's educational objectives to patients and caregivers, (2) advance the practice of medicine, and (3) improve patient outcomes. Examples may include: live local symposia, web activities and mobile applications, and print materials.
- 3) Financial support provided to fund other initiatives that can help advance healthcare practice and/or improve patient outcomes (such as grants to medical congresses/societies, fellowships, in-kind program support, etc.) as long as the Teva Policy is followed.

Independent medical education grants must not:

- o Support activities that are routine obligations of the recipient
- o Be linked directly or indirectly to support of our products
- o ~~Support education solely directed to patients~~ Provide direct financial benefit to practicing health care providers

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3.1.2 Potential Requestors

Certain organizations are eligible to request financial support from Teva. Such organizations include but are not limited to:

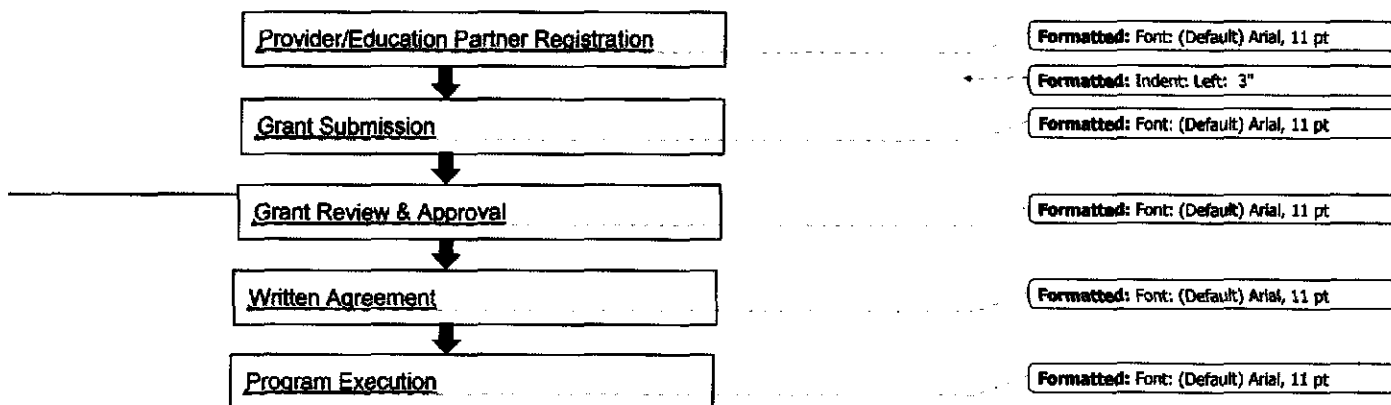
- o Accredited CME-organizations – includes CME and CPD (Providers)
- o Accredited and Non-accredited medical education/communications companies (MECCs) that regularly conduct independent medical educational events
- o Institutions, such as a universities, medical schools or large hospitals that regularly conduct independent medical educational events
- o Healthcare-related professional organizations (e.g., American Academy of Sleep Medicine, American Academy of Pain Medicine, American Society of Clinical Oncology, American Society of Hematology, American Academy of Neurology, American Association for Allergy, Asthma and Immunology)
- o Other organizations that regularly educate healthcare professionals and/or patients/caregiver (e.g., National Sleep Foundation, The Leukemia and Lymphoma Society, National MS Society, American Chronic Pain Association)

Certain persons or organizations are not eligible to receive financial support from Teva. Such organizations include but are not limited to:

- o Individual physicians
- o Private practice groups
- o Groups of physicians that have formed "foundations" or "associations,"
- o Family- or physician-controlled private foundations
- o Pharmacy Benefit Managers (PBMs)
- o Group Purchasing Organizations (GPOs)
- o Managed care organizations
- o Health plans or pharmacies
- o Providers who have had an unsatisfactory review by a Teva U.S. Medical Education team

3.2 Grant Proposal Review Process

3.2.1 Grant Process Overview



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3.2.1 Grant Program Reconciliation, Evaluation & Outcomes

- All IME grant requests must be submitted through the online Request Management System <https://tevarequests.com/>. The Request Management System serves as a repository for all relevant documentation pertaining to educational grant requests.
- Grants which fail to meet grant standards are rejected by the most senior member of the U.S. Medical Education Department.
- Grant requests for a monetary amount above the pre-specified limit, which meet the grant standards, are submitted for review and approval to the Grant Review Committee (GRC).
- Grant requests for a monetary amount below the pre-specified limit, which meet the grant standards, can be approved by the most senior member of the US Medical Education Department, unless significant queries about the request require a further review by the GRC.

3.2.2 Grant Review Process

- All Providers/Education Partners (aka Requestors) must register in the online Request Management System (RMS)
- All grant requests must be submitted through the online RMS <https://tevarequests.com/>. The RMS serves as a repository for all relevant documentation pertaining to educational grant requests.
- Grants which fail to meet grant standards are rejected by the most senior member of the U.S. Medical Education Department.
- Grant requests for a monetary amount above the pre-specified limit, which meet the grant standards, are submitted for review and approval to the Grant Review Committee (GRC).
- Grant requests for a monetary amount below the pre-specified limit, which meet the grant standards, can be approved by the most senior member of the US Medical Education Department, unless significant queries about the request require a further review by the GRC.
- All approved programs require a written agreement which is generated via the RMS and signed electronically by the Providers and any Partners who create content.
- The U.S. Medical Education Department has the ability to Request Further Information (RFI) from the Provider if more information is needed to complete the review.
- All communication with the Providers is done via the RMS. Communication of approval or denial is not official unless it comes through the RMS.

3.2.2.3 Grant Review Committee (GRC)

GRC is comprised of members of the U.S. Medical Education, Compliance and Legal departments. All GRC members must appoint a designee if unable to complete their GRC duties.

The following factors require review & approval by the entire Grant Review Committee in order for a grant request to be considered supportable:

- Full budget review to ensure expense items align with Teva's guidelines

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Comment [p1]: At what point will we have to include US Med Directors to align with the Global Policy?

- o Honoraria aligns with Teva's Fair Market Value guidelines
- o Request contains a robust Needs Assessment & up-to-date references
- o Request meets pre-established educational objectives

⊖ All GRC members must enter their approval in the RMS before a grant can be processed and paid.

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3.3 Higher level Decision Making Process (Escalation Process)

Situations may arise when a decision should be made at a higher level than the GRC because no decision can be reached to either approve or decline a Grant Request. The following process will be implemented on an as-needed basis:

- o The Head of US Medical Education will initiate a higher level decision process when a Grant Request presents an issue of conformity with well established corporate standards and objectives.
- o The Head of US Medical Education will work with the Compliance Manager of the GRC to schedule a meeting with the VP of Compliance and VP of Legal to address the issue(s).
- o The VP of Compliance and VP of Legal will have the responsibility to decide the issue(s) presented in a timely fashion and will have authority to approve or decline the Grant Request.
- o The decision to approve or decline a Grant Request in question will be communicated with the Head of US Medical Education.
- o Appropriate documentation of the decision will be made in the Request Management System.

Comment [T2]: New addition to policy 8/27/13. If this is implemented we need to inform the appropriate VP's so that they understand their roles within this policy.

3.4 Reconciliation, and Evaluation, and Outcomes

All grants will be reconciled in order to obtain actual financial accounting and program metrics/outcomes.

A sample of grants will be evaluated to ensure that the education was executed according to the grant proposal and governing guidelines and policies (specially evaluating for scientific/medical rigor, balance, bias, management of conflicts of interest, etc).

3.4.1 Financial Reconciliation

- o The financial reconciliation process is managed by the US Medical Education ~~Reconciliation Specialist~~.
- o All ~~IME~~ grant requests must be financially reconciled within 60 days post end-date of the program/event.
- o If requests are not financially reconciled and/or refunds not returned within the allotted timeframe, requestors may be subject to refusal of future submissions until such time that financial reconciliation is satisfactorily completed.

3.4.2 Program Evaluation and Outcomes Review

- o ~~IME~~ grant requests will be randomly selected for evaluation by the respective Therapeutic Area Manager.

- o The intent of the evaluation is to ensure that the program/event was fully executed as outlined in the proposed grant request and in accordance with all governing guidelines.
- o Evaluation of the program/event ~~along with review of the final outcome metrics~~ will assist in determining future support with the respective CME Provider.
- o Final outcomes/metrics are required for Medical Education activities and requested for Patient Education activities and are reviewed and assessed by the Therapeutic Area Manager

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Comment [T3]: New addition to policy 8/27/13

3.5 Conflicts of Interest

Teva may not provide a grant to a Provider or MECC if such entity provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other departments within Teva. This standard applies even if the consulting services are for one product/disease area and the grant relates to another Teva disease area of interest.

If, however, such company has established a separate affiliated company that conducts non-promotional medical education activities and there are sufficient firewalls separating the activities of the two affiliates, then Teva can provide a grant to such affiliated company even if its sister company is providing marketing or other promotional activities to Teva. Examples of such firewalls include separate personnel, office space, IT support, servers and phone lines, with communication between companies limited to company procedures and logistics. The Provider should have procedures for resolution of commercial conflict. In such instances, firewall documents must be requested and reviewed by U.S. Medical Education, prior to submission to GRC. The information provided will be evaluated, together with the grant, on a case by case basis.

4 RESPONSIBILITY

U.S. Medical Affairs, U.S. Medical Education will maintain and update this policy as appropriate.

Approving Vice President: Richey Neuman Denisa Hurtukova, VP US Medical Affairs

Is the Global document a policy or an SOP? Will the US document be a policy or an SOP? We have US work instructions that need updating too.

Do we need an acronyms and/or definitions section?

Do we need to include what we will not provide support for?

Do we need to include more detail on the components of the written agreement?

Do we need to include anything on Open Payments Reporting?

Do we need to add something in about supplemental distribution of program announcements by field personnel?

Do we need to include info on attendance at supported programs or interactions between Teva personnel and faculty? - or refer to that policy in this policy?