

POLICY GLOBAL PRINCIPLES FOR HEALTHCARE PROFESSIONAL INTERACTIONS

OBJECTIVE

The objective for the Actelion Global Principles for Healthcare Professionals Interactions (“Global Principles for HCPs”) is to provide a comprehensive overview of the most common areas for business interactions and establish compliance standards for all Actelion affiliates. In order to effectively implement the policies discussed herein, affiliates should adopt local policies and standard operating procedures (SOPs).

SCOPE AND APPLICABILITY

The Principles for HCPs applies globally to all Actelion employees, contractors, and third-parties working on behalf of Actelion (“Actelion personnel”). As such, the Global Principles for HCPs govern how Actelion personnel must interact with both HCPs and the broader community when conducting business activities.

REVIEW AND APPROVAL

Corporate Affairs and Compliance 15-Dec-15 signed ¹
CEO 14-Jan-16 signed ³

¹ Author, signs for correctness and completeness

² (Only if applicable) Reviewer, signs for control of correctness and completeness

³ Approver, signs for the release of this document

1. CONTENT

As a global organization, Actelion is committed to conducting business in a professional manner consistent with applicable laws, regulations, and industry codes including, but not limited to, those that address anti-bribery, competition, and the research, manufacturing and marketing of pharmaceutical products.

1.1 COMPLIANCE WITH GLOBAL STANDARDS AND LOCAL REQUIREMENTS

Actelion’s business practices are designed to meet global standards for compliance as well as satisfy all local legal and regulatory requirements. As such, any local Actelion policies or procedures for interactions with HCPs must be consistent with the standards set by the Actelion Global Principles for HCPs. In circumstances where local laws and regulations impose more stringent requirements, the relevant Actelion affiliate must adopt local policies and procedures to ensure compliance with these local regulations and laws.

1.2 RESPONSIBILITIES FOR IMPLEMENTATION

Affiliate General Managers are responsible for ensuring compliance with the Global Principles for HCPs at the local level, including the delegation of authority and resources to relevant function heads who shall be responsible for the implementation and oversight of appropriate processes within their respective areas of control at minimum:

- Timely review and approval of all promotional content
- Appropriateness of HCP and patient interactions
- Appropriateness of contracting and funding provided at local level
- Training on required policies and procedures, including the Global Principles for HCPs and Code of Business Conduct

2. GLOBAL STANDARDS FOR INTERACTION WITH HEALTHCARE PROFESSIONALS (HCPs)

2.1 GENERAL REQUIREMENTS

For purposes of the Global Principles for HCPs, an HCP is defined broadly as any individual who directly interacts with patients or has a role in patient care, diagnosis or treatment. This includes physicians, nurses, pharmacists, and other individuals who may not interact directly with patients, but have influence over the recommendation, purchase, prescribing or approval of Actelion products, such as third party agents, pharmacies, healthcare plan administrators or government health authority employees.

Actelion's interactions and relationships with HCPs are intended to benefit patients and to enhance patient care or the practice of medicine and are primarily structured to support:

- Promotional interactions focused on informing HCPs about the benefits and risks of approved Actelion products
- Clinical and scientific interactions focused on informing HCPs about scientific, medical, and research information related to Actelion products and disease states of interest to the Company
- Fee for service Consultant interactions focused on obtaining necessary services from qualified HCP experts.

2.2 SEPARATION BETWEEN PROMOTIONAL AND NON-PROMOTIONAL ACTIVITIES

Promotional and non-promotional activities must be distinct and separate from each another.

- Activities and interactions which are motivated by the objective to sell or market Actelion products are considered promotional
- Activities and interactions that are conducted to support scientific initiatives are considered non-promotional and must not have the promotion of Actelion products as a purpose.

When interacting with HCPs, Actelion personnel must conduct their activities in a manner consistent with the underlying promotional or non-promotional purpose.

2.3 CONTRACTING WITH HCPs

HCPs may be engaged by Actelion to provide needed knowledge and expertise to support research, medical or commercial business objectives. In order to ensure compliance with country anti-bribery statutes and industry codes, contractual arrangements must not be entered into

for the purpose of influencing the use, purchase or recommendation of Actelion products. As such, all HCP consulting arrangements must meet the following requirements:

- Legitimate Need – Consulting arrangements must be based on a legitimate business need that requires HCP expertise
- Licensure and Expertise – HCP consultants subject to licensure must have an active professional license in good standing as per local country requirements
- Fair Market Value – Payments to HCP consultants must be based on local fair market value (FMV) rates as determined by the local affiliate from where the HCP resides
- Written Agreement – HCP consultants must have a fully executed consulting agreement in place that describes the specific scope of services and payment terms.

2.4 PAYMENT OF HONORARIA AND FEES FOR SERVICES

In exchange for the performance of agreed upon consulting services, Actelion compensates HCPs in the form of honoraria and fees based on objective fair market value rates from where the HCP resides. All payment terms and conditions, including a specific description of the scope of proposed services must be documented in a contract. Fair Market Value principles apply even where Actelion engages an HCP through the services of a third party (e.g., CRO, meetings and event planner, marketing agency).

Actelion does not pay honoraria, fees or otherwise compensate HCPs for their time and attendance at events sponsored by third party medical associations, such as scientific congresses or meetings. However, this restriction does not prohibit Actelion from paying honoraria to HCPs for their consulting services related to an Actelion-sponsored program that is conducted in connection with or adjoining to a medical conference (e.g., engaging an HCP to serve as a speaker at an Actelion sponsored symposia at a third party medical conference or engaging an HCP to serve as an advisor at an Actelion sponsored advisory board that occurs in relation to a third party medical conference).

2.5 BUSINESS MEALS AND EDUCATIONAL ITEMS

Consistent with local legal and regulatory requirements, business meals may be provided to HCPs in connection with an informational product or disease presentation or business discussion. These meals must be based on a legitimate business purpose and in a venue conducive for a business environment. Consequently, facilities intended primarily for entertainment and leisure activities are prohibited.

Actelion personnel may also provide educational items that are intended to advance the education of an HCP regarding relevant disease states or treatment options, provided that such items are offered or provided on an occasional basis and are modest in value consistent with local standards.

Business meals and educational items may never be offered or provided to a HCP with the intent to inappropriately influence an HCP's decision to prescribe, dispense, recommend, purchase, supply or administer Actelion products.

Due to evolving country legal and regulatory requirements pertaining to the provision of business meals and educational items to HCPs, Actelion personnel should confirm the most current requirements with their supervisor, and in case of uncertainty, with the local Compliance Champion, Corporate Compliance Office.

2.6 GIFTS AND ENTERTAINMENT

Actelion does not provide or offer gifts for the personal benefit of HCPs that are unrelated to the practice of medicine. This includes payments in cash or cash equivalents, such as gift certificates, tickets to sporting or entertainment events, and electronic items for personal use.

In some countries, if allowed under local law, an inexpensive customary gift unrelated to the practice of medicine may be given on an exceptional basis to a HCP in acknowledgment of significant national, cultural or religious occurrences. Cash or cash-equivalents may never be offered or provided as part of a customary gift.

2.7 INTERACTIONS WITH HCPS CONSIDERED PUBLIC OFFICIALS

HCPs working at public hospitals or government institutions may be defined as 'public officials' and may be subject to additional legal and regulatory requirements.

3. EVENTS AND MEETINGS

3.1 SCIENTIFIC AND EDUCATIONAL OBJECTIVES

The purpose for symposia, congresses and other promotional, scientific or professional meetings ("Events") for HCPs organized or sponsored by Actelion is to provide scientific or educational information and/or inform HCPs about products.

3.2 PROMOTIONAL INFORMATION AT INTERNATIONAL EVENTS

Actelion seeks to ensure that the regulatory status of Actelion products is clearly communicated to HCPs at in-

ternational events. Promotional information about Actelion products displayed at booth exhibits or distributed to participants at international scientific congresses and symposia may refer to Actelion products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that all the following conditions are observed:

- Host country regulations should permit such an arrangement,
- The meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place,
- Promotional materials for Actelion products not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not approved locally,
- Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally, and
- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

3.3 SPONSORSHIP TO ATTEND SCIENTIFIC CONGRESSES OR MEETINGS

The sponsoring of HCPs to attend scientific congresses and meetings provide an important opportunity for HCPs to continue their medical education and learn about advances in potential product options for patients. Where permitted under legal and regulatory requirements from a HCP's home country, Actelion may sponsor the cost for an HCP's attendance at a scientific congress or meeting. Sponsorship costs may include expenses for appropriate travel and lodging, meals, and congress or meeting registration fees and must be approved by the local Compliance Champion. As noted above, however, Actelion does not pay honoraria, fees, or otherwise compensate HCPs for their time and attendance at scientific congresses or meetings sponsored by third parties.

3.4 APPROPRIATE VENUES FOR ACTELION SPONSORED EVENTS

Venues for Actelion sponsored meetings or events must be conducive to and consistent with the business purpose for the meeting or event. The location selected for the event should not be a leisure, tourist or holiday destination. Meeting facilities, such as hotels, should be selected

based primarily on their conference facilities, location and business services. For this reason, “5 star” or “luxury” designated facilities may not be used unless a valid business purpose exists and prior approval is provided by the Compliance Champion from the host country.

If a third party scientific congress or meeting is taking place at a venue or location that would not otherwise be considered suitable under the above standards, Actelion may nevertheless sponsor a meeting or event at the same time and venue or location for logistical purposes, if permitted by host country regulations and the third party conference organizer.

It is not permitted to organize or sponsor an Actelion event or meeting involving HCPs at a venue outside the HCP’s home country (“international event”), unless the following conditions apply:

- The majority of HCPs participating in the event are based outside the host country, but given the countries of origin of most of the participants, it makes greater logistical sense to hold the event in the host country; or
- Given the object or subject matter of the event, or the audience for the event, it makes greater logistical sense to hold the event in the host country.

3.5 MEALS, TRAVEL, LODGING AND EXPENSES

HCP related expenses for meals, lodging and transportation should be reasonable, modest and consistent with the policy requirements established by the local Actelion affiliate hosting the event or meeting. However, even if HCP expenses fall within the required policy limits, additional consideration should be taken as to whether the meal, travel or lodging could be perceived as lavish or excessive under local country standards.

Actelion does not pay for expenses related to HCPs’ guests.

The following provides additional guidance for HCP expenses:

- Actelion may pay for the reasonable lodging and accommodation of HCPs who serve as consultants or advisors to Actelion or, where permitted, have been sponsored by Actelion to attend a scientific congress or meeting
- Actelion should pay lodging only for the nights necessary for the HCP to perform the agreed-upon services or attend the scientific congress or meeting. Actelion will not pay for extra nights lodging unless there are extraordinary objective circumstances (e.g., an extended stay is unavoidable due to flight restrictions)
- Travel expenses for HCPs should be consistent with the

policy requirements from the HCP’s home country. Generally, business class airfare should only be provided for a flight longer than five hours duration

- Unless otherwise approved by the Compliance Champion from the HCP’s home country, Actelion should schedule HCP travel based solely on the required anticipated dates for HCPs attendance at the Actelion event, meeting or scientific congress. Actelion does not schedule travel for HCPs to accommodate their personal travel plans and activities.

3.6 REVIEW AND APPROVAL OF CROSS-BORDER HCP ENGAGEMENTS

As a global organization, Actelion affiliates, including headquarters, may engage HCPs to travel to another country for necessary and valid consulting services or, where permissible, to sponsor their attendance at a scientific congress or meeting. Prior to initiating the HCP contracting process or the offering of a sponsorship opportunity, the responsible Actelion associate seeking the HCP engagement must complete an Actelion HCP Engagement Form (HEF) and submit it to the Compliance Champion from the HCP’s home country for notification and approval. The HEF and contact information for affiliate Compliance Champions is provided on Actelion InSite.

4. PROMOTIONAL ACTIVITIES

4.1 PROHIBITION ON PRE-APPROVAL AND OFF-LABEL PROMOTION

Actelion is committed to marketing and promoting its products responsibly to ensure that HCPs receive accurate, fair, balanced and relevant information required to make fully informed decisions about patient care and treatment. As such, Actelion will not engage in promotional communications or activities for Actelion products or indications prior to their approval by the appropriate regulatory authorities.

This provision is not intended to prevent the right of the scientific community and the public to be informed concerning scientific and medical progress. Nor, is it intended to restrict a proper exchange of scientific information by Actelion personnel concerning an Actelion product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences.

4.2 PROMOTIONAL INFORMATION AND CLAIMS

All promotional information and claims must be consistent with the prescribing information as approved by the local regulatory authorities. Additionally, all claims must be accurate, fair, balanced and not misleading and substantiated.

ed based on data from clinical studies. Unsupported comments about competitors or their products are prohibited. Generally, comparative superiority claims versus competitor products are allowed only if they are based on peer-reviewed published data or reflected in the approved product information and must be checked according to local regulations.

Promotional materials used in interactions with HCPs must not contain information intended to promote unapproved Actelion products or unapproved characteristics of approved products.

4.3 PRINTED PROMOTIONAL MATERIALS

All Actelion printed promotional materials must include as a minimum:

- the name of the Actelion product (normally the brand name),
- the active ingredients, using approved names where they exist,
- the name and address of the Actelion affiliate or its agent responsible for marketing the product,
- date of production of the advertisement,
- “abbreviated prescribing information” which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions, and side-effects.

4.4 PROMOTIONAL MATERIALS REVIEW

All Actelion promotional materials must be reviewed and approved by an appropriate review committee in accordance with local requirements in order to ensure that Actelion product information is accurate and consistent with the current prescribing information as approved by the local regulatory authorities. Where required by local regulations, records of promotional materials must be maintained and filed with the relevant health authorities.

The use of unapproved promotional materials or altering of approved materials without appropriate review committee review and approval is prohibited. Actelion Global Marketing is responsible for the adoption of policies and procedures to support review of global brand materials. Affiliate Marketing departments are responsible for the adoption of policies and procedures to support ARC review at the local country or region level.

5. ON-PROMOTIONAL INTERACTIONS

Non-promotional interactions with HCPs help to provide an opportunity to exchange scientific and/or educational information with HCPs in order to enhance patient care

and the practice of medicine. Such interactions must be separate and distinct from promotional activities and not interfere with the independence of HCPs.

5.1 SCIENTIFIC EXCHANGE WITH HCPs

To advance medical, clinical and research objectives, Actelion Medical, Clinical and Research personnel engage in scientific discussions with HCPs, which may include discussions about unapproved Actelion products or unapproved indications.

The information exchanged in these scientific interactions must be accurate, non-promotional, and presented in a fair and balanced manner. Moreover, Actelion Medical, Clinical and Research personnel may not make specific therapeutic recommendations regarding individual patient care or treatment, nor may they promote Actelion products or disseminate promotional materials to HCPs.

5.2 ADVISORY BOARDS

The purpose of engaging HCPs as consultants or members of advisory boards is to receive input on specific medical, clinical, research, marketing or other important business objectives. Accordingly, engaged HCPs must be experts in a given field. Advisory boards may not be used as a vehicle to market, sell, or promote Actelion products or otherwise build relationships with HCPs.

Advisory board engagements must be based on a written contract containing clear tasks and responsibilities, compensation and confidentiality stipulations. Fees and expenses must be reasonable and fair market value in relation to the services rendered. The number of HCPs participating at an advisory board should be limited to the minimum number necessary to achieve the advisory board’s objectives.

5.3 INTERACTIONS WITH CLINICAL TRIAL INVESTIGATORS

Designated Actelion personnel may approach and interact with HCPs to assess their interest and qualifications to participate in Actelion-sponsored clinical trials. Clinical trial protocols may not be shared with potential investigators until an Actelion Confidentiality and Disclosure Agreement is executed.

5.4 INVESTIGATOR SPONSORED STUDIES

In some countries, Actelion may support or fund independent research involving Actelion products by a third party HCP through an Investigator Sponsored Study (ISS) grant. An ISS grant is an Actelion-funded grant that is provided in response to an external investigator’s proposal to conduct clinical, healthcare-economic, or outcomes research related to an Actelion product or therapeutic area of interest.

Investigators must independently generate the proposal, research protocol, and budget, which are subject to review and approval by CIRAC.

Designated Actelion Medical, Clinical and Research personnel may engage in scientific discussions with potential investigators in order to provide guidance on the overall ISS submission, review and approval process, follow up on the status of agreed upon ISS milestones, or respond to general ISS inquiries.

Outside of these interactions, Actelion personnel should not assist in the development of the ISS protocol or proposal or otherwise make any assurances or promises to potential investigator regarding the approval of their ISS proposal.

5.5 ACTELION SPONSORED CLINICAL TRIALS

Actelion is committed to the well-being and personal integrity of all study participants. As such, Actelion conducts clinical trials based on scientifically designed protocols, which balance the potential risk to study participants with the possible benefit to participants and to society. Actelion conducts all clinical research in accordance with ICH Good Clinical Practice (GCP) standards, local legal and regulatory requirements and principles that have their origin in the World Medical Association's Declaration of Helsinki.

5.6 MARKET RESEARCH

Actelion conducts market research consistent with legal and regulatory requirements as well applicable industry codes governing market research activities, such as the European Pharmaceutical Market Research Association (EPHRA) guidelines and the CASRO Code. Market research may not be used as a vehicle to promote Actelion products. This restriction does not prevent the use of information derived from market research from being utilized to help inform or drive subsequent Actelion promotional activities.

6. MEDICAL EDUCATION GRANTS, SPONSORSHIPS AND CHARITABLE DONATIONS

Actelion contributes to the enhancement of medical knowledge by providing financial support to promote HCP or patient education and awareness in disease and research areas of interest to the Company. Actelion support may include:

- Educational grants to independent medical education providers that deliver unbiased medical education to HCPs
- Charitable donations to non-profit third party organiza-

tions, such as patient organizations involved in patient education, advocacy, and support programs that benefit the public and improve patient care

- Sponsorships to third parties for major scientific conferences or for patient advocacy and charitable events.

6.1 MEDICAL EDUCATION GRANTS

Medical education grants provide HCPs with the opportunity to continue to learn about disease states and advancements in disease treatment areas of interest to Actelion. Actelion supports medical education activities that are non-promotional, balanced and objective. In some regions, such medical education activities must be developed independent of company sales and marketing influence or control and be delivered entirely by independent third party medical education providers.

6.2 SPONSORSHIPS TO THIRD PARTY ORGANIZATIONS

Sponsorships are payments made to third parties in exchange for tangible items controlled by Actelion, such as booth space in an exhibit hall, advertising, banners, websites, or similar public displays of the Actelion logo. For this reason, sponsorships may be driven by Actelion Sales and Marketing objectives and activities. All sponsorships should be approved by the local Compliance Champion.

6.3 CHARITABLE DONATIONS

Actelion may provide financial and in-kind contributions to non-profit charitable organizations that are established to support causes related to patient healthcare, education, and advocacy.

Charitable organizations that seek funding must provide documentation of their non-profit status. All charitable donations must be reviewed and approved by the local Compliance Champion.

7. TRANSPARENCY REPORTING

Actelion is required under various country and regional laws and codes to track and publicly disclose certain types of monetary and in-kind transfers of value to designated HCPs. Such transfers of value may include, but are not limited to meals, fees and honoraria for consulting services, educational items or courtesy gifts, sponsorships, grants and payments related to travel and lodging. These laws and codes are intended to provide the public with insight into interactions between the pharmaceutical industry and HCPs.

It is important for Actelion personnel to understand the business responsibilities for accurately capturing all required HCP spend information, which may vary depending

on the type of transfer of value (e.g., consulting payments to an HCP versus a business meal with an HCP). Actelion is committed to having business processes in place to capture the required information and disclose all payments in accordance with these laws and codes.

8. REPORTING A COMPLIANCE CONCERN

Actelion personnel who reasonably believes that there has been a violation of the Global Principles for HCPs must report it immediately to their supervisor, their local Compliance Champion, or the Corporate Compliance Office, or through the Company's anonymous Global Compliance Helpline.

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Actelion Pharmaceuticals Ltd is a global biopharmaceutical company headquartered in Allschwil/Basel, Switzerland. Actelion concentrates on discovering, developing and marketing innovative drugs for high unmet medical needs. The company is quoted on the SIX Swiss Exchange (tickersymbol: ATLN).