

Global Code of Practice for Promotion		Version:	1.0	
and Interaction		Effective Date:	Mar 10, 2022	
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Version supersedes	Reasons for change		
N.A	New Policy		



## Global Code of Practice for Promotion and Interaction

Global Legal & Compliance (GLC) Version: 1.0

Effective Date: Mar 10, 2022

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## 1. Purpose

Dr. Reddy's Laboratories Limited including its subsidiaries and joint ventures (referred to as "Dr. Reddy's" or "Company") is committed to the highest legal, moral and ethical standards in conducting its business. Dr. Reddy's has adopted the Code of Business Conduct and Ethics (referred as "COBE"), which lays down the principles and standards that govern the actions of the Company and its employees.

Being an integral part of global pharmaceutical industry, Dr. Reddy's remains committed to providing latest scientific and educational knowledge to **HCPs** to ensure that they have up to date comprehensive information about diseases they treat and patients have access to the medicines they need. The purpose of this Global Code of Practice for Promotion and Interaction (this "Global Marketing Code" or "Code") is to set out standards for the ethical interaction and promotion of Company's products amongst HCPs and **HCIs** in compliance with the applicable laws and this Code.

Promotion of all products should be backed by adequate, unbiased and truthful technical/clinical data. Interactions with HCPs should be appropriate and intended to benefit patients and improve the patient outcomes.

## 2. Scope & Applicability

This Code provides a minimum set of global standards and procedures that are to be followed by the Company, its employees and any other Company Representative, including but not limited to persons retained by way of contract with third parties, in relation to interactions with the HCPs & HCIs while engaging in sales, research, marketing and promotional activities for and on behalf of the Company. All such activities must be conducted in accordance with applicable local laws, regulations and applicable industry codes, which may be more stringent than the requirements of this Code.

This Code is to be construed as the foundation for all local country specific Code of Practice for Promotion and Interaction ("Country Specific Marketing Codes") and relevant Standard Operating Procedures (SOPs) which may provide additional requirements for all activities. Therefore, this Code is to be read and applied along with and in conjunction with the Country Specific Marketing Codes and relevant SOPs.



## 3. Principles

Company is committed to conducting interactions with HCPs responsibly and with integrity. At times, we face circumstances where the right path is unclear. The following core ethical principles are designed to guide our daily decision-making, so we can:

- Demonstrate our commitment to acting with integrity
- Align our actions to ensure that we conduct our business in an ethical manner, and
- Protect the interest of all company stakeholders.

These five principles apply to all HCP interactions, even to situations not specifically addressed in the policy.

#### 3.1 Patient Centricity

Our interaction with HCPs is intended to benefit patients and enhance the practice of medicine and we are committed to providing them with timely and accurate information to assist in treatment decisions including product, scientific and medical, and safety information. The Company treats all patient information with confidentiality, transparency and respect and where required obtains informed consent.

#### 3.2 Legitimate Funding

We provide monetary and in kind support including grants, donations and sponsorships only to legitimate organizations and which is aligned with our scientific interests. All funding must be in line with local laws and regulations.

#### 3.3 Clear and Transparent Purpose

Being part of the pharmaceutical industry, Dr. Reddy's conducts various promotional and non-promotional activities. All our activities have clear and transparent objectives which are accurate, truthful, not misleading and must not interfere with the independence of HCPs.

We promote our products only for indications that have been approved, cleared or authorized by the relevant regulatory/governmental agency without in any way influencing or appearing to influence the decisions of the HCPs.

#### 3.4 Ethical Engagements

To ensure the safe and proper use of our products, information provided to our customers and HCPs on the packaging label, inserts, local prescribing information, or sales and advertising material must be in compliance with all applicable laws, standards and regulations that apply to our products, and supported by scientific evidence where relevant.

Interacting with HCPs and HCIs is an important aspect of Company making safe, innovative and reliable products and services available to patients. We may engage with HCPs and others to provide



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necessary legitimate services to help us research, enhance, develop and promote our products. Any compensation must be for a bona fide service, consistent with Fair Market Value (**FMV**), properly documented and accounted for, and disclosed where required.

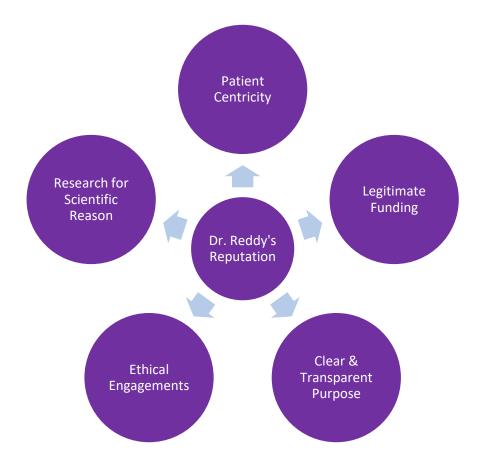
We do not offer anything of value to a HCPs to influence their professional judgment or purchasing practices in favor of our products. We avoid creating any conflicts of interest. Allowable items of value, when provided to HCPs, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

#### 3.5 Research for Scientific Reason

We conduct research to enhance patient care by addressing the unmet need. We have the utmost regard for the safety and confidentiality of participants in our research and ensure that they are not subjected to undue risks, and that they understand the risks, nature and purpose of the research.

We are committed to following established ethical and scientific standards for conducting research.

Research and development activities must never be promotional in nature.





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## 4 Policy

#### **General Requirements-**

We interact with HCPs on a regular basis for variety of legitimate business reasons, including research, education, promotion, obtaining professional services or advice to help us research, develop, enhance, and promote our products. We also provide financial assistance to third party organizations to support, research, educational, charitable, and community efforts, and to support industry, professional, and patient organizations.

When involved in any of these activities, we consistently uphold our commitment to integrity by:

- Following the five core ethical principles as set out above.
- Meeting the expectations and minimum requirements outlined below for HCP interactions, as well as in other company policies and procedures that apply to various activities.
- Meeting all requirements under applicable local laws and/or industry codes.
- Conducting Company activities in a manner as to avoid actual or perceived interference with the independent decisions HCPs make on behalf of patients
- Documenting our business activities appropriately in compliance with company and legal requirements
- Properly recording and tracking and, where required by local law, disclosing and reporting any payments
  or transfer of value (TOV) to HCPs and HCls.
- Not offering, promising, approving, or providing any opportunity or anything of value with the intent to induce improperly or reward HCPs for any decisions related to company products and services, and
- Following all legal requirements and prohibitions that apply when interacting with HCPs who are Public Officials, including employees or representatives of a government or public international organization.

## 4.1 HCP Engagement

- a. Engagement of a HCP must not be done in exchange or as a reward for the prescription, purchase, supply, dispensing or administration of our products. If a third party is engaged in any activity, business teams to reach out to Global Legal & Compliance Department for appropriate due diligence and agreement/documentation, as applicable.
- b. The Company Representatives seeking to engage a HCP for the provision of services must ensure that proper documentation and approvals are obtained in compliance with this Code.
- c. Refer to **Annexure I** for documentation. Employees must also refer to the documentation, review and approval of all activity/inputs (including honorarium to HCPs, materials to be utilized for the events etc.) in the applicable Country Specific Marketing Codes.
- d. **Due Diligence**: The employee seeking to engage a HCP for the provision of services must ensure that no potential conflict of interest exists and documentation and approvals are collected in compliance with this Code. The Company must only engage HCP to provide services provided a legitimate need has been identified. Refer to **Annexure III** for Conflict Check Process.
  - Prior to or while signing a contract, a potential HCP must undergo anti-corruption check and self-declaration by filling out and signing a HCP Due Diligence Questionnaire (self-declaration form), (Annexure II). Filled Due Diligence Form need to be reviewed/approved as per local country



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process. For any situation with conflict, Regional Compliance Officer must need to review/approve the engagement.

- e. **HCP Classification**: The Company engages only to HCPs Classified under the criteria which are directly related to the company's identified needs. These criteria ensure that HCP selection and remuneration level are in line with qualifications, expertise and experience to provide relevant services. Refer to **Annexure IV** for HCP classification criteria.
- f. **Honorarium**: Honorarium payment for HCP Services must be reasonable and at FMV in relation to the services rendered. Maximum engagement of an individual HCP in a financial year should not exceed 100 paid hours as per FMV. To ensure that maximum engagement hours are not exceeded, HCP Payments need to be tracked during the financial year by using HCP Payment Tracker (Annexure VI) or any other digital mode. Refer to Country Marketing Codes/SOPs for guidance on calculation of FMV.
- g. **Approvals**: HCP engagement must be approved as per local country process by using Concept Note HCP Consulting/Advisory Services/ISP Justification/HCP Sponsorship Form **(Annexure V)**.
- h. **Cross-country engagements** of HCPs must be approved by respective Regional Compliance Officer (RCO) responsible for HCP's practicing country for compliance with local laws, regulations and industry codes.
- i. Government HCPs (Public Officials): The Company may engage Government HCPs in accordance with the requirements of applicable local law, industry codes and Country Specific Marketing Codes. While engaging Government HCPs, it is recommended to obtain No-objection Certificate (NOC) or any other documentation through which intimation to the employer of Government HCPs can be demonstrated. For example a letter/communication/acknowledgement from Head of the Department/Supervisor/Personnel Department of the HCPs.
- j. Contracting: After obtaining all internal approvals, HCP engagement must be documented in a written agreement that is executed and binding on all relevant parties before services commence. The latest templates of HCP services agreements, approved by Legal must be used for both local HCPs & foreign national HCPs and include Anti-Bribery Anti-Corruption (ABAC) Clauses and relevant provisions.

#### 4.2 Continuing Medical Education (CME)

The Company may with the intention of providing latest scientific and educational information about disease/wellness and its' management or updated product information with supporting clinical evidence, engage an HCP as a faculty at a Company organized CME (physical or digital). The respective Company Representative shall ensure that all applicable approvals have been obtained and appropriate agreements have been executed pertaining to the CME.

Competitions (including raffles and lotteries), gifts, recreation and entertainment are not permitted. Any quizzes must relate to scientific/medical knowledge or skill in the relevant disease area.

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CMEs to be organised within the same country of origin/practice of the participants. The maximum duration of CMEs should not exceed two days.

#### 4.2.1 Types of CMEs

#### Medical Education (ME) Events:

Focus of these events is on educating on disease/wellness and management paradigms with a primary objective of helping HCPs to update their scientific knowledge in disease conditions and/or wellness aspects where the Company has strategic interest.

Scientific content in these events would focus on multiple aspects of disease/wellness, including patho-physiology, risk-factors, screening, diagnosis, prevention, management, complications etc. There is a balanced discussion on all available therapeutic options when medical management is discussed. Drugs are referred to by generic name.

#### **Branding at Medical Education Events:**

- Corporate (Dr. Reddy's logo) branding can be done inside and/or outside the hall
- No product branding permitted inside the hall
- Product branding is permitted only outside the hall
- For digital Medical CMEs, during the session (inside the hall), only Corporate (Dr. Reddy's logo) branding is allowed as aesthetically suitable.

#### **Product Education (PE) Events:**

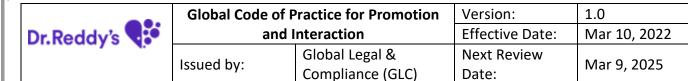
These are events conducted to educate the HCPs on product details including but not limited to molecular structure, mechanism of actions, pharmacokinetics/dynamics, efficacy, safety, key features and benefits and instructions on appropriate usage of the product as per local regulatory approval of the product.

#### **Branding at Product Education Events:**

- Corporate (Dr. Reddy's logo) branding can be done inside and/or outside the hall
- Product branding is permitted inside and/or outside the hall
- For digital Product CMEs, product branding is allowed as aesthetically suitable.

#### 4.3 International Speaker Program (ISP)

a. The purpose of conducting an ISP is to impart scientific education on disease/wellness and its management aspects or appropriate product usage based on approved indications and updated clinical evidence.



- b. An International Speaker is classified as a HCP whose country of affiliation is outside the country where the event is being held.
- c. Corporate and Product branding principles mentioned in Section 4.2 (Continuing Medical Education) to be followed.
- d. HCP engagement must be approved as per local country process by using Concept Note HCP Consulting/Advisory Services/ISP Justification Form **Annexure IV**. Due Diligence to be performed as described in Section 4.1 by using HCP DD Questionnaire **Annexure II**.
- e. As ISPs require cross-country engagements of HCPs, approvals must be obtained from respective Regional Compliance Officer (RCO) responsible for HCP's practicing country for compliance with local laws, regulations and industry codes.

## 4.4 Departmental Meetings

- a. Company may participate in medical meetings of hospitals/institutions/medical colleges if the focus of these meetings is on educating on disease/wellness and management paradigms with a primary objective of helping HCPs to update their scientific knowledge in disease conditions or wellness related aspects where the Company has strategic interest.
- b. Company may participate in such programs by providing meals, scientific content, digital projector and/or digital platform.
- c. Corporate (Dr. Reddy's logo) branding can be done inside and/or outside the hall
- d. No product branding permitted inside the hall
- e. Product branding is permitted only outside the hall
- f. For digital meetings, during the session (inside the hall), only Corporate (Dr. Reddy's logo) branding is allowed as aesthetically suitable.

#### 4.5 Advisory Board Meetings

- a. Advisory Boards are necessary to answer legitimate scientific/business questions.
- b. Company may organize advisory boards to obtain advice that can best be obtained by bringing together a group of experts.
- c. All Advisory Board members must have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting.
- d. No product branding allowed in any Advisory Board. Only corporate branding can be done.
- e. HCP engagement for Advisory Boards must be approved as per local country process by using Concept Note HCP Consulting/Advisory Services/ISP Justification Form **Annexure IV**. Due Diligence to be performed as described in Section 4.1 by using HCP DD Questionnaire **Annexure II**.

#### 4.5.1 Types of Advisory Boards

#### Scientific Advisory Boards:

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- a. Objective of Scientific Advisory Boards is to obtain insights into scientific medical aspects of the disease/wellness aspects, its diagnosis and management including current practices as well as to understand perspectives on future directions or the views on product and its data in question.
- b. These advisory boards must be driven by Medical Affairs team (including selection of HCPs) with only logistics support from the Commercial team. All interactions in these meetings with HCPs will also be driven by Medical Affairs team.
- c. Commercial team can participate as observers (only if off-label information is not being discussed) and are allowed to participate through genuine scientific questions which have not been raised or answered.
- d. Scientific Advisory Boards pertaining to medical evidence generation should be conducted by Medical Affairs or their appointed designee only [for e.g., contract research organization (CROs)].
- e. HCP selection for Scientific Advisory Boards must be driven by Medical Affairs and sales/commercial teams shall not have any role in the same.

#### **Commercial Advisory Boards:**

- a. Objective of Commercial Advisory Boards can be done to obtain insights on marketing strategy and its execution, pricing strategy, access model/programs and/or portfolio.
- b. These advisory boards should be driven by commercial team in the presence of Medical Affairs team to address any scientific queries on product, disease/wellness aspects and therapy.

#### 4.6 HCP Sponsorship

- a. Where permitted under applicable local laws and/or Industry Codes, Company may support HCPs to attend Local / Regional/ National/ International Third Party Events/Conferences and Dr. Reddy's organized Events, CMEs etc. as Faculty or Delegates.
- b. Company may support HCPs to attend such Events to address their educational and scientific needs.
- c. Any Sponsorship provided to Individual HCPs must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any company's product. In all instances, we must ensure that HCP Sponsorship does not interfere with HCP's independence.
- d. Selection of HCPs for participation in such Events to be based on educational and scientific needs. No hospitality or travel or other attendant facilities should be provided to family members/persons accompanying any HCP or to any delegates. No payment to be made to compensate HCP for time spent in attending any CME/ Events (National / International) as a delegate. Sponsorship to HCPs is limited to the payment of travel, meals, accommodation, and registration fees. Agenda of the Conference/Event/Meeting should be educational & scientific in nature and relevant to the therapeutic area of the HCPs.
- e. The Company may sponsor Government HCP's in accordance with the requirements of applicable local law, industry codes and Country Specific Marketing Codes. While sponsoring Government HCP's, it is recommended to obtain No-objection Certificate (NOC) or any other documentation through which intimation to the employer of Government HCPs can be demonstrated. For

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example a letter/communication/acknowledgement from Head of the Department/Supervisor/Personnel Department of the HCPs.

- f. HCP Sponsorships need to be approved by using Concept Note **Annexure V** or any other digital mode.
- g. HCP Sponsorships to be tracked during the financial year by using HCP Sponsorship Tracker **Annexure VI** or any other digital mode.

## 4.7 HCP Train the Trainer (TTT) Program

- a. Where permitted under applicable local laws and/or Industry Codes, Company may support HCPs to attend Local / Regional/ National/ International Third Party Events/Conferences and Dr. Reddy's organized Events, CMEs etc.
- b. Where the HCP is attending the Event/Conference a delegate, post Event, it is recommended to do knowledge dissemination as part of HCP TTT Program. If HCP is attending above mentioned events as a Faculty, then knowledge dissemination is not required.
- c. The Company may enter into a HCP TTT Program with a HCP only for Company initiated medical/product education events.
- d. The purpose of a HCP TTT Program is for an HCP to gain and disseminate knowledge to other HCPs, and if needed, a HCP may be supported to gain the knowledge through attending Company initiated medical/product education events, such support may be provided for enabling the HCP to perform his/her services.
- e. A HCP TTT Program should be done only with the intention of assisting the HCP to acquire the latest updated knowledge in the organizational strategic area of interest and the HCPs' area of expertise which he / she shall disseminate to other HCPs to enable them to improve patient outcomes.
- f. Any Sponsorship provided to Individual HCPs and HCP TTT Program must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any company's product. In all instances, we must ensure that HCP Sponsorship does not interfere with HCP's independence.
- g. No hospitality or travel or other attendant facilities should be provided to family members/persons accompanying any HCP.
- h. No payment to be made to compensate HCP for time spent in attending any CME/ Events (National / International) as a delegate. However for services obtained as part of HCP TTT Program (dissemination), Honorarium can be paid as per FMV. The HCP shall disseminate the knowledge gained to other HCPs within 12 months post attending such event/conference through conducting atleast 1 cascade session (speaker in physical or digital CME, participant in Focused Group Discussion etc.) or by submitting Scientific Material, Videos, Case Study, Publications (newsletter, review article, authorship of book/chapter) etc. on the basis of learning at conference if HCP is attending the event/conference as a Delegate. If the HCP fails to deliver the commitments for the dissemination, it is recommended not be consider this HCP for any subsequent TTT or HCP Sponsorship engagement till such time the dissemination activities are completed.



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#### 4.8 Promotional & Non-Promotional Materials & Communications

Company supports the right of the scientific community and the public to be informed concerning scientific and medical progress. Therefore, where allowed by local laws, regulations and industry codes, Company may exchange scientific information. This may include communications at scientific events, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents and public health organizations.

<u>Promotional Materials & Communications:</u> Upon receipt of marketing authorization, Company may interact with customers, either directly or via a third party, to promote Company products, related features, and benefits. Company may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content must be accurate, fair, balanced, truthful and not misleading, based on adequate substantiation and consistent with the scope of the relevant product's marketing authorization.

Products must only be promoted consistent with approved labeling, as approved by the local regulatory authorities. Anyone promoting a Company product must be trained and have sufficient knowledge of the product to provide full and accurate product information.

Any materials used for purposes of the interaction must be approved as per local Country Promotional Material Approval process and in accordance with local laws, regulations and industry codes.

<u>Non-Promotional Educational Materials & Communications:</u> Company may also provide non-promotional educational materials based on educational and scientific needs of the HCPs. For example, scientific articles, snippets from journals, scientific books, medical modules etc. as part of mass distribution and scientific communication. For individual requests for Medical Books, Journals and Modules, please refer to Section 4.11.

Request for information on unapproved drugs and indications (off-label): Company may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs, patient organizations, and other stakeholders. Only the Medical Affairs function may provide such information in response to these requests. Company employees who receive unsolicited requests for off-label information must forward such requests to the Medical Affairs function. The response provided by the Medical Affairs function, including any materials, must be accurate, not misleading, not promotional in nature, related solely to the subject matter of the

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request, and in compliance with local laws, regulations and industry codes. The Medical Affairs function should maintain written documentation of unsolicited requests and responses.

## 4.9 Disease Awareness/Education Programs & Medical Screening/Diagnostic Camps

Disease awareness information includes booklets on diseases, media campaigns, mailings to patient organisations and disease awareness advertising.

The provision of disease awareness information must not be intended or designed to encourage the patient to ask their HCP to prescribe a Rx product.

- a. Company employee may conduct non-promotional disease awareness or education programs to increase awareness or education about health, disease, and their management directed to patients, general public, and HCPs.
- b. Company may also partner with the medical community for holding Camps to create community disease or wellness related awareness and screening with an objective of disease prevention and / or treatment. For this purpose, the Company may facilitate the organization of a Camp in association with a HCP or a HCI.
- c. Camps are organized for the benefit of general public/patients to increase awareness and diagnosis of disease or wellness related aspects. Where HCPs are engaged, such engagement should not be done with a view towards using the HCP to induce patients to use the products of the Company or to induce the HCP to prescribe the Company's products.
- d. No Company employee should involve in interacting, screening, pricking or collection of samples from patient.
- e. No patient personal information should be collected by the company employees during the camp.
- f. No Product branding is allowed during such Camps. Only corporate branding is allowed.
- g. Refer to applicable Country Specific Marketing Codes for monetary limits for camps.
- h. Camps are of the following 3 types:
  - Company initiated camps conducted at a neutral venue involving disease or wellness related awareness/education and/or screening/ diagnosis
  - Company initiated camps conducted at HCPs place of practice for screening/ diagnosis with or without disease or wellness related awareness/education
  - Company initiated camps conducted at HCPs place of practice involving only patient screening/diagnosis.
- 4.9.1 Company initiated camps conducted at a neutral venue involving disease or wellness related awareness/education and/or screening/ diagnosis
  - a. To be conducted at a neutral venue i.e. located at a venue which is away from HCPs place of practice.

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- b. HCP to conduct a disease or wellness related awareness/educational talk and/or screening/diagnosis of patients.
- 4.9.2 Company initiated camps conducted at HCPs place of practice for screening/ diagnosis with or without disease or wellness related awareness/education
  - a. Can be conducted at HCPs place of practice.
  - b. HCP to conduct screening/ diagnosis with or without disease or wellness related awareness/educational talk.
- 4.9.3 Company initiated camps conducted at HCPs place of practice involving only patient screening/diagnosis without any expenses except consumables
  - a. Can be conducted at HCPs place of practice.
  - b. HCP to conduct screening/diagnosis.

#### 4.10 Market Research

Market Research is a non-promotional activity intended to gather information from HCPs, Patients, Consumers, or other representative group of stakeholders about a product, disease area, or other topic of interest to Company.

- a. The sole purpose of the market research must be to collect data and not be a means to identify, promote and/reward HCPs. Market research must rely on scientific research methodologies such as sampling, data collection and analysis techniques, and not on methods which risk discrediting or reducing confidence in the pharmaceutical industry.
- b. Market research must not be used as a disguised form of sales promotion and engagement activities, and in itself, the research must not have an objective of influencing the opinions of the informant. The research design should be done in such a way that the data is unbiased and non-promotional.
- c. All market research activities where HCPs are involved in advisory capacities/ consultants / researchers/ any other feedback providers treating doctors or in any other professional capacity should be performed in a manner ensuring the best interest of the patients, integrity and freedom of HCPs.
- d. Participants in market research may receive a fee for service based on FMV. Market research must be conducted in accordance with applicable local laws and regulation of the respondent's country as well as local/regional/ market research local procedures. Any documents related to Market Research (e.g. Market Research Questionnaire, Protocol etc.) should be pre- approved through local promotional material approval procedure including Medical Affairs approval.
- e. Market Research for gathering competitive intelligence at molecule & brand level can also be conducted.

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- f. The Market Research outcomes must be documented appropriately.
- g. All Market Research activities should be conducted through a third party only. Any third party engaged for such Market Research (involving interaction with HCPs) should undergo Third Party Due diligence process. Any adverse events or products complaints identified during market research must be reported internally in a timely manner, as per applicable local laws and company procedures.

#### 4.11 Medical Modules, Books and Journals

- a. Medical Books and Journals, print or digital, are educational items or resources primarily aimed to enhance HCP's knowledge so as to improve patient outcomes and for the purposes of:
  - Latest scientific information in a particular medical field;
  - Supporting medical research; and
  - Furthering continued medical education in the field of healthcare industry, wellness, diseases and/or treatments.
- b. Subscription of society/association memberships for the HCP is not allowed.
- c. Cost of Medical Modules, Books and Journals per financial year per individual HCP shall not exceed US\$ 700 (excluding taxes). Refer to applicable Country Specific Marketing Codes for local limits.
- d. Any exception for the limit of Medical Modules, Books and Journals require additional approval from Regional Medical Affairs Head apart from normal local exception process.
- e. Corporate branding can be done on all Medical Modules, Books & Journals.
- f. No Product branding allowed in Medical Modules. Only Corporate branding (e.g. Dr. Reddy's logo) can be done.
- g. For any requests coming from individual Government HCPs, request letter or No-Objection Certificate (NOC) from the HCI need to be obtained. Alternatively, such Books, Journals or Modules can be given to HCIs only.

#### 4.12 Cultural Courtesy Items

- a. Cultural Courtesy Item(s) can be given to HCP on special occasions defined under the applicable Country Specific Marketing Codes.
- b. Cash or cash equivalent benefits or any cash transactions with HCPs are strictly prohibited.
- c. Personalized items and gifts for the personal benefit to HCPs and/or their family members such as sporting or entertainment invitations/admits/passes/tickets; lunch/dinner, electronic items, standalone entertainment, recreational activity or hospitality services are **not** permitted.
- d. Employees are not allowed to use their personal funds (i.e. without seeking company reimbursement) for procuring Cultural Courtesy Items.



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- e. Only Corporate branding (e.g. Company logo) can be done appropriately on all Cultural Courtesy Items. No Product branding to be done on the item and/or the outer box/secondary packaging etc.
- f. Maximum value limit for Cultural Courtesy Items shall not exceed US\$ 200 (excluding taxes) per HCP per annum. For each occasion, the value limit shall not exceed US\$ 50 (excluding taxes). Refer to the applicable Country Specific Marketing Codes for local limits.

#	Allowed Events
1	HCP's Birthday
2	HCP's Wedding Anniversary
3	Doctors Day/Nurses Day/Therapy Day (eg. World Diabetes Day etc.)
4	Local Festivals like Diwali / Eid / Durga Puja / Christmas etc.
5	New Year/Chinese New Year etc.

#	Allowed Items
1	Non-alcoholic Perishable Food Items (Cakes, Chocolates, Dry Fruits, Sweets etc.)
2	Greeting Cards
3	Flowers, Bouquets etc.
4	Local festival related items like Candles, Colours, Diya, Country Flags etc.

## 4.13 Items of Medical Utility & Brand Reminders

#### **Brand Reminder (BR)**

A Brand Reminder is a non-monetary item given for in-clinic promotional purpose relevant to the medical profession/pharmacy and which is intended to be used to remind the HCP of the Company product.

#### Items of Medical Utility (IMU)

Items of Medical Utility may be given to HCPs which are beneficial to enhancing the provision of medical services and patient care.

#### **General Principles:**

- a. Items such as stethoscope, gloves, prescription pads, blood pressure machines, as part of brand reminders/Items of Medical Utility are **not** allowed.
- b. Employees are not allowed to use their personal funds (i.e. without seeking company reimbursement) for procuring any Brand Reminders / Items of Medical Utility.
- c. Product brand name and/or corporate brand name (e.g. Dr. Reddy's logo) should be affixed appropriately on all Brand Reminders and Items of Medical Utility and/or the outer box/secondary packaging etc.



- d. Product brand name cannot be affixed on any part of Brand Reminder or Item of Medical Utility which comes into contact with the patient for their treatment/examination. In such cases, only corporate branding must be done on the Brand Reminder or Item of Medical Utility and/or the outer box/secondary packaging etc.
- e. Maximum value limit for Brand Reminders and/or Items of Medical Utility shall not exceed US\$ 15 (excluding taxes) per HCP per occasion. Brand Reminders/Items of Medical Utility shall not exceed three per brand (including its family)per brand per month per HCP (maybe calculated annually). Refer to the applicable Country Specific Marketing Codes for local limits.

#### 4.14 Third Party Sponsorships

- a. Company may participate in meetings which are organized by the Medical Associations/Institutions/Hospitals ("Organizer") where the agenda is controlled by the Organizer.
- b. Participation must be subject to the scientific content being reputable and aligned to Company's scientific or medical interest and must be open and transparent.
- c. Sponsorship amount requested must be aligned to the tariff card and /or official letter of the Organizer.
- d. No event shall be sponsored for any entertainment, leisure or sporting activity.
- e. Only approved materials (Leave Behind Literatures, Visual Aids etc.) must be used in booth / stall.
- f. Representative at the booth/stall possess knowledge on products consistent with prescribing information.
- g. All Third Party Sponsorships should be in compliance to applicable local laws and approved as per local country procedures.

## 4.15 Branding Space / Advertisement in Journals / Books

Company may obtain product/corporate branding space in reputed journals/books (print/digital) where the content of such journal/book is in line with the Company's scientific/wellness related interests. ABAC Due Diligence on Publishers of such books/journals to be performed before purchasing advertisement/branding space.

#### 4.16 Patient Support Programs (PSPs)

- a. Patient Support Programs (patient support programs / patient adherence programs) are conducted to enhance therapy access to eligible patients.
- b. All PSPs to be conducted through a third party only.
- c. ABAC Due diligence of such third party to be conducted by Compliance prior to the engagement.
- d. Approvals for PSPs must be obtained from Medical Affairs, Global Legal & Compliance (GLC), Finance, Pharmacovigilance (PV) and any other stakeholder as applicable as per local country approval process. Refer to Activity Request Form (ARF) for PSP (Annexure VIII).

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e. Before the initiation of PSP, the third party must be trained on Company's Pharmacovigilance (PV) practices and Adverse Events (AE) reporting forms to be shared with the third party with timelines for timely collection and reporting of AE information. AE reporting process with third party must be detailed out in the agreement.

## 4.17 Samples

- a. In accordance with local laws and regulations, free product samples may be supplied to HCPs authorized to prescribe that product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused.
- b. Samples shall be provided in consonance with the following principles:
  - i. Free samples of drugs should not be supplied to any person who is not qualified to prescribe such product. It should be handed directly to person qualified to prescribe or permitted to receive the samples on their behalf.
  - ii. Sampling is done for the purpose of providing experience in dealing with such a product and should be done in a reasonable quantity.
  - iii. Product Samples must not be used to reduce the cost of treatment, provide discount, and negotiate product inclusion in hospitals or formulations or to disguise commercial discounts.
  - iv. Samples provided must be for designated therapeutic use. All samples should be accompanied with the most up-to-date product information as approved under Applicable Law.
  - v. Expired physician samples should be destroyed in the same manner as other commercial drugs. In no case, should expired samples be distributed to HCP.
  - vi. Samples must be given in compliance to applicable local laws and/or industry codes.
  - vii. Samples to be given in reasonable quantity and should not be used to inappropriately influencing promotional and prescription decisions of third parties/HCPs.
- viii. Samples should not be used to impose as a requirement or condition on HCPs for promotion or prescription.
- ix. Samples of prescription products (Rx) should not be provided in any Company events.

#### 4.17 Grants and Donations

Company may provide Grants or Donations to external organizations. We must fund responsibly, in a manner that maintains our reputation, aligns with our mission "good health can't wait" and extend people's lives, advance medical or scientific knowledge, and supports communities.

Grants and Donations must only be given to legitimate organizations, never to individuals. It must have a clear and defined purpose. Funding must be reasonable and legitimate in light of the activity being funded and properly tracked, documented, reported, and accounted for, as required by local laws, regulations and industry codes.

For any Grants & Donations requests, please refer to Dr. Reddy's *Grants & Donations Policy*.



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#### 4.19 Venue, Travel & Hospitality

- a. All Company events / meetings with HCPs must be held at an appropriate venue that is conducive to the scientific or educational objective and purpose of the meeting. The venue must be reasonable and not extravagant.
- b. In case of domestic travel, business class is not allowed. In case of international travel (where the non-stop air travel is more than 6 hours one way) business class is permissible with prior written approval from the Management Council (MC) member.
- c. Modest accommodation can be booked for HCPs who are being engaged in the capacity of a faculty (speaker/ chairperson/ panellist/ moderator etc.).
- d. For Company organized events, refreshments and/or meals incidental to the main purpose of the event may be provided within reasonable meal limits established locally, however no entertainment or other leisure/social activities should be provided or paid for by the Company. Local meal limits should be based on cost of living in the country. If HCPs home country applicable local law, industry codes and Country Specific Marketing Code provide for more restrictive meal limits, then those limits need to be followed.
- e. Subject to any more restrictive affiliate requirements, alcoholic beverages may be ordered or served during meals and refreshments provided by Company, when they are appropriate to the business environment and reasonable and modest in quantity. Standalone alcoholic beverages are not an appropriate form of business refreshment or entertainment.
- f. No hospitality or travel or other attendant facilities should be provided to family members/persons accompanying any HCP or to any delegates. No payment to be made to compensate HCP for time spent in attending any CME/ event (National / International) as a delegate.
- g. Interactions with public officials may be subject to additional laws, regulations and industry codes.

#### 4.20 Interaction with Pharmacy Chains:

For any interactions in connection with prescription products with pharmacy or pharmacy chains, the procedures regarding interactions with HCPs and HCls including, for example, Meals, Travel, and Entertainment, Brand Reminders, and Professional Services, and all of the specific subject matter guidance on HCP and HCl interactions still apply.

The company may sign contracts with local pharmacy chains for the purpose of ordering marketing services or conducting bonus campaigns.

#### a. Marketing services

As a general practice, and if this is not restricted by local law, the Company can hire pharmacy chains to provide the following type of marketing services:

- (i) presentation (merchandising)
- (ii) branding the interior of the pharmacy



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(iii) distribution of brochures

(iv) renting space for the location of the Company's panel

The Company must ensure that marketing services are a real need, a fair market price is paid and that records are maintained.

For example, the correct documentation of brochure distribution services will include an agreement for such services, a contract for printing brochures, a certificate of receipt of brochures by a chain of pharmacies, a distribution report of all or a part of the brochures, a photo report (optional) of the distribution of the brochures in each chain pharmacy and a certificate of receipt for services rendered.

#### 5 Definitions

For the purpose of this Code, following definitions will apply:

"Company Representative" means all employees, directors, officers, agents, service providers, consultants of the Company.

"CME"- Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge skills, and professional performance and relationships that a physician uses to provide services for patients, the public or the profession.

"Donation" is a benefit granted by Company to legitimate organizations for a specified purpose, where Company does not expect to receive any benefit, consideration or service in return.

"Events" means all types of scientific congress, conferences, symposia, meetings or any type of similar activity, including but not limited to experts meetings, roundtable meetings, training meetings etc. organized or sponsored by pharmaceutical company.

#### "Government Official" means and includes:

- Elected or appointed official, employee (full time or part time) or person acting on behalf of or representative of any government or government owned or government controlled business enterprise;
- b) Officer or employee or person acting in official capacity for or on behalf of a public international organization (like United Nations, World Bank or International Monetary Fund etc.);
- c) Holding an office of a political party; or a candidate for political office;
- d) Medical and scientific personnel including HCPs, qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government;
- e) Any other person who is considered to be a public official according to applicable laws, regulations and industry codes.



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The term "Government" is meant to include all levels and subdivisions of government (i.e., local, regional or national and administrative, legislative or executive).

"Grants" means a support either financial or in-kind, given to a legitimate organization in response to an unsolicited request to support activities in which the Company will have no other active participation or involvement.

"Grants Committee" All request for Grants would be reviewed by a committee generally comprising of leads/designees of Legal/Compliance, Finance, Group Country Head and Medical Affairs.

"HCI" or "Health Care Institution" means any entity or facility, including any institution, foundation, association, or organization, which employs HCPs, or any site where HCPs provide health care to patients. HCIs are often end purchasers or customer accounts for DRL products used or prescribed by HCPs. Examples of HCIs include hospitals, group practices, surgical centers, public clinics, private clinics, and pharmacies which sell prescription DRL products.

"HCP" or "Health Care Professional" means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell or administer a Pharmaceutical Product.

"Honorarium" means Payment for a service, such as making a speech or being an Advisory Board Member. Such payments are made as per Fair Market Value (FMV).

Non-promotional, Scientific Materials ("NPSM") Content of such materials is limited to scientific facts and does not include product brand name/logo/imagery/tag line. Examples of such materials include scientific reprints, disease related communications, congress updates, patient education material etc.

Promotional Materials ("PM") Such materials include information sufficient enough for educating a Health Care Professional (HCP) towards his decision to prescribe. This information includes brand name/logo/imagery/tag line and product indication(s), with or without further scientific information or product claims. Examples of promotional materials include but not limited to, product visual aids, leave behind literatures, detailers, product advertisements, product reminders, product monographs, etc. Promotional materials are intended to encourage the rational scientific usage of the Company's medicinal products.

"Pharmaceutical Product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription



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of, or under the supervision of, a HCP, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

"Product Samples" are provided by DRL at no charge for trial or evaluation by Patients or Consumer are known as product sample.

"Promotion" refers to the informational and marketing activities undertaken, organized or sponsored by a pharmaceutical company, through whatever medium or channel, with the objective of providing information to the HCP about medicine, its appropriate use and scientific information, and to support medical research and education.

"Recipient" means the organization requesting or applying for a Grant from the Company.

"Third Party Event Organizers" means organisations such as associations, societies, HCIs who organize 'events' i.e. organisers other than pharmaceutical companies.

## 6 Implementation

#### 6.1 Training

Employees must familiarize themselves with this Code and the relevant Country Codes. Employees must be trained in line with the Company-wide compliance training curriculum. Additional training requirements for Employees and third parties conducting business on behalf of Company may be conducted locally at country level at periodic intervals.

#### 6.2 Third parties

Third parties involved in conducting activities covered by this Policy and on behalf of Company are expected to comply with this Code, applicable laws and to adhere to ethical business practices. Company employees contracting third parties are ultimately responsible for how third parties conduct these activities on behalf of Dr. Reddy's.

#### 6.3 Breach of this policy

Failure to comply with this Code may lead to disciplinary and other actions, up to and including termination of employment.

#### 6.4 Reporting potential misconduct/non-retaliation

Any Employee with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the Ombuds process. Employees who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

#### 6.5 Exceptions

No exceptions can be granted from compliance with applicable laws, regulations and industry codes. The Chief Compliance Officer (CCO) will review all policy exceptions related to this **Code**.



#### 6.6 Responsibilities

It is the responsibility of every Dr. Reddy's Manager and Supervisor to adhere to this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the employees reporting to him or her.

If employees are not able to find guidance on a particular question, do not assume that the interaction or activity is permitted. Employees must consult their manager and/or Compliance team if they are unsure about whether a proposed course of action will comply with any of Dr. Reddy's standards or applicable laws and regulations. All Company employees are responsible for adhering to this Policy.

#### 6.7 Adverse Event Reporting Process

The Qualified Person for Pharmacovigilance (QPPV) or National Responsible Person for Pharmacovigilance (NRP) or designee of the country is responsible for ensuring all adverse event reports concerning Dr. Reddy's products authorized in the country are collected, processed and if applicable reported according to local regulations.

All adverse event information should be forwarded to the India and Emerging Markets Pharmacovigilance Centre within 24 hours of receipt, but no later than the next working day. Day 0 (clock start) is the day when any employee at the affiliate office or third party working on behalf of the Dr. Reddy's affiliate receives minimal reporting criteria on a suspected adverse event to a Dr. Reddy's product.

Minimum information to be gathered from the reporter are (RAMP):

- a. Reporter information (Name, Profession/ qualification, address/email, contact number).
- b. Adverse Event.
- c. Medicine Product Name (Dr. Reddy's Product).
- d. Patient Information (first letter of first and last name, age/date of birth, sex).

All adverse event should be reported within 24 hours of receipt, but no later than the next working day at <a href="mailto:pharmacovigilance@drreddys.com">pharmacovigilance@drreddys.com</a> and/or <a href="mailto:customerservices@drreddys.com">customerservices@drreddys.com</a>. You can also call and report on Toll Free Number: 18004250014.



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## Annexure I: Documentation Checklist

Activity	Pre-Event Documentation	Post-Event Documentation
Continuing Medical Education (CME)	<ul><li>Agenda</li><li>Executed agreement with the faculty</li></ul>	<ul> <li>Photographs/Screenshots of the event</li> <li>Original bills of expenses (if any) incurred</li> <li>Attendance sheet (physical/digital) of all attendees</li> </ul>
International Speaker Program (ISP)	<ul><li>Agenda</li><li>Executed agreement with the faculty</li></ul>	<ul> <li>Photographs/Screenshots of the event</li> <li>Original bills of expenses (if any) incurred</li> <li>Attendance sheet (physical/digital) of all attendees</li> </ul>
Departmental Meetings	<ul> <li>Request Letter from the hospital/institution/medical college</li> <li>Confirmation Letter to the hospital/institution/college from the Company</li> </ul>	<ul> <li>Photographs/Screenshots of the event</li> <li>Original bills of expenses (if any) incurred</li> </ul>
Advisory Board Meetings	<ul> <li>Agenda</li> <li>Executed agreement with the faculty</li> </ul>	<ul> <li>Minutes of Meeting</li> <li>Photographs/Screenshots of the event</li> <li>Original bills of expenses (if any) incurred</li> <li>Attendance sheet (physical/digital) of all attendees</li> </ul>
HCP Sponsorship as Faculty	<ul> <li>Written request (email or letter) from the HCP for the support.</li> <li>Invitation/conference agenda of the HCP as a faculty.</li> <li>Executed Agreement with the HCP prior to the activity</li> </ul>	• Nil
HCP Sponsorship as Delegate	<ul> <li>Written request (email or letter) from the HCP for the support.</li> <li>Agenda of the conference.</li> <li>Executed Agreement with the HCP prior to the conference.</li> </ul>	<ul> <li>Photographs / Screenshots of the event.</li> <li>Original bills of expenses (if any) incurred.</li> <li>Attendance sheet (physical/digital) of all attendees.</li> </ul>

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Train the Trainer (TTT)	<ul> <li>Agenda</li> <li>Executed agreement with the faculty</li> </ul>	<ul> <li>Photographs/Screenshots of the event</li> <li>Original bills of expenses (if any) incurred</li> <li>Attendance sheet (physical/digital) of all attendees</li> </ul>
Health Camps	<ul> <li>Pamphlet/banner with date, time and venue of the camp (except camps under section 4.9.3)</li> <li>Agreement (only for camps under section 4.9.1) with the HCP prior to the camp</li> <li>Agreement with third party (if any) prior to the camp</li> </ul>	<ul> <li>Letter of Appreciation cum         Acknowledgement from the HCP         (except camps under section 4.9.3)</li> <li>Original bills of expenses (if any)         incurred (except camps under section         4.9.3)</li> </ul>
Market Research	<ul> <li>Agreement with third party (if any) after conducting Compliance Due Diligence by GLC</li> <li>Market Research Questionnaire</li> </ul>	<ul> <li>Confirmation from business team for completion of final deliverables.</li> <li>Invoice copy from third party (if any).</li> </ul>
Books & Journals	<ul> <li>Request Letter from HCI on their letterhead</li> <li>Request Letter from HCP on Letter Head for individual requests for a specific Medical Books and Journals requirement of the HCP</li> <li>NOC for requests from Government HCPs</li> </ul>	Acknowledgement of receipt of the Medical Books and/or Journal from the HCI
Medical Modules	<ul> <li>Agreement with the third party (after compliance due diligence, if applicable) with clear scope of roles and responsibilities</li> </ul>	
Third Party Sponsorship Conference	<ul> <li>Request         letter/agenda/brochure         from Organizer on their         letter head</li> <li>Executed agreement with         the Organizer prior to the         activity</li> </ul>	



Branding	• Request Letter and/or tariff • Copy of the journal/book with the
Space/Advertisement	card from the requester on branding
in Journals / books	letter head
	Confirmation Letter from
	the Company
Patient Support	Due Diligence Report of the
Program	third party
	Agreement executed with
	the third party before
	launching the program
Samples	Details of product name and    Not Applicable
	quantity of samples given to
	each sales representative



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## Annexure-II: HCP Due Diligence Questionnaire - ABAC

(Suggested Format)

Dr.Reddy's (Company) being a global company ensures compliance with all applicable laws, regulations in the respective jurisdiction where it conducts business. As part of the company's due diligence process, this questionnaire needs to be filled by a potential / existing Health Care Professional (HCP) to check possible legislative and internal limitations which can influence company's association with the respective HCP.

Company shall use the information provided below strictly for due diligence purposes and not for any of its commercial advantage against the entity or individual. The storage and retention of this information will be carried out in accordance with the Company's policies and procedures. Failure to provide requested information may make the HCP ineligible to partner with the Company.

Note: If you are uncertain as to the meaning or applicability of any identified terms, restrictions, or disclosure requirements, you should consult with your principal contact of the company before undertaking this questionnaire.

1	Full Name, Contact information (Email, phone number):		
2	Registration Number Issued by and date of Issuance		
3	Address of work place/ Place of employment and Position		
4	Qualification / Scientific degree		
5	Are you the author or co-author of scientific papers? If yes, mention details.		
6	Are you a public official?  If "yes", mention the position and place of employment.	Yes No	
7	Do you occupy a position in state government or municipal or local authorities?  If "yes", mention the position and place of employment	Yes No	



8	Do you occupy positions in any enterprise or organizations that fully or partially	Yes	No
	funded by the state / government budgets?		
	If "yes", mention the position and place of employment.		
9	Are you currently in military service?	Yes	No
	If "yes" mention your position /rank.		
10	Are you a member or representative of any political party or candidate for political office occupation?	Yes	No
	If "yes", mention details		
11	Do you have any role / responsibility namely: participate in inspections/ or advise state authorities / or take decisions on license issuance which can influence commercial operations of the company	Yes	No
	If "yes", provide details.		
12	Do you have an authorization to sign invoices/ bills or take decisions on purchases of products /services for your organization? If "yes", provide details	Yes	No
13	Is any of your immediate family, relatives or friends employed by the company'?	Yes	No
	If "yes", mention full first name and position.		
14	Do you have a license / permit to practice medicine in any country rather than currently residing	Yes	No
	If "yes", mention the country and the license number		

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15	Are you aware of any legal actions against you or your organization, criminal or otherwise?"  If "yes" please mention.	Yes	No 

## **Authorization:**

I authorize the company and its subsidiaries, affiliates, agents & partners to verify the information

stated in this application and I understand that as part of the verification, the company may share this information with its representatives and the information will be treated in accordance with the relevant data protection law.
I
Signing this application, I confirm that I am neither employee of the enforcement agency and not a person who can influence decisions that apply to the company for state tenders or licence requirements.
Lastly, I confirm that conclusion of my engagement with the company and delivery of such services do not violate any applicable laws and does not create conflict of interests to the detriment of the patient. I further confirm that in event of a potential conflict of interest at my place of work I shall notify the company and postpone the delivery of engagement until clearance obtained from my place of work and waiver of conflicts from your company
Full Name and Signature of the HCP:
Date: DD//MM/YYYY
******************
Internal Procedure:
Name of the Brand Manager/ Regional Manager (initiator of the request / contract)

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## Annexure-III HCP Conflict Check Process

- A. DRL must ensure that the HCP will not have a conflict of interest by providing services to DRL.
- B. HCPs must fill in the self-declaration questionnaires to confirm / provide following:
- i. There is no conflict of interest once the agreement is entered into
- ii. They are authorized or are allowed to enter the contract. Government HCPs shall provide No-Objection Certificate (NOC)/Communication from Institute. If they are practicing in both government and private practice, NOC will be required.
- iii. Examples of HCP Conflict:
- HCP holding positions with govt. agencies, entities or hospitals
- HCP have any influence which can help DRLs commercial business
- Positions held by HCP family members (e.g., spouse, children, parents, siblings) that may have an impact on DRL's business (e.g., hospital administration, regulatory body, health fund);
- Any ownership control interest in an entity that has business with government in relation to healthcare and any ownership in an entity that provides services or products to DRL (self, spouse, parent, sibling)
- Any kind of allegations against them which may later harm DRL reputation
- If any conflict arises in future, they shall notify DRL immediately

This list is illustrative in nature and detailed checks provided in DD form

- C. After going through the questionnaire if we ascertain that they can influence the parameters of government or government related tenders then we should not engage with such HCPs. If we are going to engage with HCP, then level 1 check to be initiated
- D. Level 1 check by DRL on DD DRL Regional compliance team to do a general check using google, local regulatory websites and their / business knowledge on HCP to validate if what all data provided is correct. If any doubt or problem with data provided by HCP, then level 2 check to be initiated.
- E. Level 2 check by 3rd party: A detailed DD will be conducted by an independent professional to ascertain that data provided is correct plus find out if there is anything else that is not disclosed for example corruption or regulatory case or bank defaults etc.



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## Annexure-IV Suggested Criteria for HCP classification

Criteria	International	National	Regional	Local
Citizenship	Foreign	National	National	National
Scientific Degree	Doctor of Medical Science (MD/MS or Higher)	Doctor of Medical Science (MD/MS or equivalent (e.g. MRCP/MRCS or FRCP/FRCS)	Doctor of Medical Science (MD/MS or equivalent (e.g. MRCP/MRCS or FRCP/FRCS)	Licensed HCP (e.g. MBBS/MD or equivalent
No. of Year of Experience	15+ years of clinical experience on the topic	10+ years of clinical experience on the topic	7+ years of clinical experience on the topic	5+ years of clinical experience on the topic
Journal Publication in peer reviewed publications or textbook authorship		10+ Journal Publication in Peer reviewed publications or textbook authorship	7+ Journal Publication in Peer reviewed publications or textbook authorship	Journal Publication in Peer reviewed/Local Journal
Association   Medical Scientific   Society Sub		Part of National Medical Scientific Society, Sub Committees	Any History of Regional Medical Scientific Society , Scientific Group (e.g. provisional/state medical association)	Member of well- respected and influential local community.
Position	President/Past President of International Society/Association.  Current or Previous Position as full professor of Teaching Institution.		Current or Previous experience as clinical professor/Associate professor of Teaching Institute.	Well-respected and influential with local community, Medical expertise, reputation or knowledge and experience in the therapeutic area.



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#### **Annexure-V:**

Concept Note - HCP Consulting/Advisory Services/
International Speaker Program (ISP) Justification/HCP Sponsorship Form
(Suggested Format)

#### Note:

- Please be as descriptive as possible and attach additional pages, as required.
- Any updates or changes to the Business Justification Form require re-submission to the Compliance Department. Put "NA" to any of the sections which are not applicable.
- If you have any questions with regard to the completion of this Form, please contact the Compliance Department.

#### **SECTION I - EVENT INFORMATION**

Please identify the nature of the fee-for-service arrangement (i.e., advisory board meeting, speaker training, consulting arrangement) or HCP Sponsorship arrangement:

Proposed Event Date(s):

Proposed Venue and Location:

## **SECTION II - BUSINESS JUSTIFICATON (Fee-for-service Arrangement)**

What is the business objective and purpose of the fee-for-service arrangement?

Attach a preliminary agenda and schedule of events, or list of discussion topics.

How will each health care professional's advice / output be collected and documented?

A description of how the Company will use the output of the advisor's/consultant's services?

Have fee-for-service arrangements addressing the same topic been held before? If so, explain why additional fee-for-service arrangements are needed to achieve your business objective.

## **SECTION III - BUSINESS JUSTIFICATION (HCP Sponsorship Arrangement)**

What is the business objective and purpose of the HCP Sponsorship?

Attach a preliminary agenda and schedule of events, or list of discussion topics.

How HCP Sponsorship will benefit HCPs and bring better patient outcomes?

Describe any plans how the knowledge gained by HCPs attending the event will be disseminated to other HCPs in the country?

Whether HCP Sponsorships are allowed in the country as per applicable local laws/industry codes?



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#### **SECTION IV - CONSULTANT SELECTION & DUE DILIGENCE**

Who selected each HCP and who reviewed his/her credentials? (Attach CV(s) or other documents supporting his/her credentials.)

Whether **Due Diligence** has been performed for each HCP?

Have you obtained services from any of the proposed HCPs during last 12 months? If yes, share details (Event date & honorarium paid)

Do we have a written agreement with each HCP who is acting as a service provider? YES / NO / SOME OF THEM

HCP Name	State(s) Licensed	State License Number(s)	National Provider ID #	Title / Specialty	HCP Name

## **SECTION V - FMV PAYMENT**

Identify the FMV compensation you are planning to offer each heath care professional for his/her services.

Describe how you determined the FMV compensation and attach any supporting documentation.

Will the HCP be provided anything other than a FMV fee-for-service payment? **YES / NO If the answer is "yes," specify:** 

Employee Requestor:
Signature:
Requestor Printed Name:
Date:
Medical Affairs Approver:
Signature/Email Approval:



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Medical Affairs Approver Printed Name:
Date:
Regional Compliance Officer:
Signature/Email Approval:
Regional Compliance Officer Printed Name:
Date:

A copy of this completed form must be filed with the relevant contract / contract renewal for each HCP.



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# Annexure-VI HCP Payment Tracker (Suggested Format)

Below details need to be maintained for each HCP:

- a. HCP Name, Address and License No.
- b. If HCP is a government employee
- c. If the Due Diligence questionnaire has been completed by the HCP
- d. HCP Classification has been completed
- e. Any other relevant details

Only HCPs listed in the HCP Tracker can be engaged by the Company for rendering of services.

HCP Payment Tracker need to be maintained by Country Finance.

	HCP Payment Tracker (Amount in Local Currency/USD)													
S.No	HCP Name	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														



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## Annexure-VII HCP Sponsorship Tracker

(Suggested Format)

(Country Marketing Team need to maintain HCP Sponsorship Tracker)

S.No	Meeting Name	Meeting Dates	Meeting Venue	HCP Name	HCP Type (Speaker/Delegate)	Hospital Name	Sponsorship Type (Stay, Registration, Travel)	Sponsorship Amount (in USD)	No. of deliverables as per agreement	Date on which CME/RTD Conducted (after attending the Conference)
1										
2										
3										
4										
		<u> </u>								



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# Annexure-VIII Third Party Sponsorship Confirmation Letter (Suggested Template)

(E.g. Stall, Scientific Session, Scientific Symposium) not for Individual HCP Sponsorship

Note: Please fill in all blanks highlighted in yellow, remove highlights and brackets and delete all text shown in red, before signing and sharing with the third party.

(Via Email/Letter Head)

To,

Name and Address details as per the request letter

[Name of the Institution mentioned in the request letter]

**Sub:** Confirmation of sponsorship

Ref: Request Letter for sponsorship from [name of the Institution] dated [insert date]

Dear [insert name as per the request letter]

This is with reference to your letter dated [insert date of request letter] where you have requested Dr. Reddy's to sponsor [name the event which is being sponsored] to be held on [insert date/s when the event will be held] at [insert location] in the field of [insert the therapeutic area]. We are pleased to confirm our sponsorship of the abovementioned programme for an amount of [insert sponsorship amount] which we understand you will utilise only for the purpose of the event mentioned above. If this sponsorship is intended to be used for any purpose that is not in compliance with local laws or for any other purpose other than the event mentioned above, please let us know in writing immediately. In such event. Dr. Reddy's reserves its right to withdraw the sponsorship.

This is to reaffirm that this sponsorship is not intended to influence any decision you/your members/owners/representative may make regarding the prescription of Dr. Reddy's medicines or to otherwise influence Dr. Reddy's business.

We will pay the sponsorship by cheque or by wire transfer for an amount of [insert sponsorship amount] in the name of [insert the name of the Institution to whom the sponsorship will be paid – **never to an individual HCP**] as per the details mentioned in your request letter.

Kind regards	Acknowledge & Accepted by
For and on behalf of	For and on behalf of
(mention full Dr. Reddy's address and entity name)	(mention Third Party name)
[Name and Designation]	Name and Designation



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## **Annexure-IX**

## Activity Request Form (ARF) for Patient Support Program (PSP)

(Suggested Format)

Date of Request			
Requester Employee Name			
Employee ID			
Country			
	Marketing		
Department	Medical		
	Strategy Team		
Activity type	Patient Assistance/Adherence Programme		
Background	Need assessment of the activity		
Objective	Purpose of Conducting this activity		
Process/ Methodology	Name of 3rd party conducting PAP		
	Selection criteria for the third party		
	Is the due-diligence done for 3rd party?	Yes/No If Yes, attach the report. If no, please contact GLC.	
	Is data-privacy assessment done for 3 <sup>rd</sup> party?	Yes/No If Yes, attach the report. If no, please contact Data Privacy team.	
	Total budget of the activity		
Outcome	Any other point  Expected impact on patient outcome from the activity		
	Signature		
Country Head Review/Approval	Country Head Name		
neview/hpprovar	Remarks		
	Date		
	Signature		



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Approval Matrix	Medical Head Name
(Medical, Finance, Compliance, Legal	Remarks
and	Date
Pharmacovigilance signatures in	
Parallel)	Signature
	Finance Head Name
	Remarks
	Date
	Signature
	Regional Compliance Officer Name
	Remarks
	Date
	Signature
	Legal Head Name
	Remarks
	Date
	Signature
	Pharmacovigilence Head Name
	Remarks
	Date



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## **Annexure X: CME Attendance Sheet**

(Suggested Format)

CME Attendance Sheet				
Meeting Type:	Meeting Type: Date of Meeting:			
Topic:				
Speaker Name:	Venue:			
S.No.	HCP Name	Signature		



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## Annexure-XI Global Policy Exception Approval Form

(For seeking any policy exceptions to this policy, respective Regional Compliance Officer (RCO) need to use this form and obtain written approval)

Regional Compliance Officer (RCO) Name:		
Deta of Decrees		
Date of Request:		
Activity type		
Explanation for Policy Exception		
0 0 1 11		
Group Country Head Name:		
Approval Remarks:		
Date & Signature		
Managament Commell (MC) Manakan Nama		
Management Council (MC) Member Name:		
Approval Remarks:		
Date & Signature		
Chief Compliance Officer (CCO) Name		
Approval Remarks:		
Approvai Kemarks:		
Date & Signature		
(** Approvals from other relevant stakeholder's would	be obtained on case to case basis)	
1 1-pp. oralo j. on other relevante standing of would be obtained on case to case basis;		



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## (Annexure-XII) Local Deviation/Exception Approval Form

(If there are any omissions to the processes laid down under this Code, the requestor shall seek written approval by submitting a duly filled Local Exception/Deviation Approval Form)

Employee Name:	
Employee ID:	
Function: (e.g. Marketing, KAM etc.)	
Date of Request:	
Exception / Deviation (Strike out	
the non-applicable)	
Activity type	
Promotional Meeting (Continuing Medical	
education)	
ISP(International Speaker Program)	
HCP Sponsorship	
Honorarium to HCP	
Third Party Sponsorship Conference	
Cultural Courtesy Items	
Brand Reminder	
Samples	
Books and Journals	
Market Research	
Grants	
Any other activity	
Explanation for exception/deviation	
Group Country Head Name:	
Approval Remarks:	
Date & Signature	
Date & Signature	
Daviewal Fireman Hand Name	
Regional Finance Head Name: Approval Remarks:	
Date & Signature	
Date & Signature	
Regional Compliance Officer Name**	
Approval Remarks:	
Date & Signature	
zato a digitatui e	
(** Approvals from relevant stakeholder's would be obtained on case to case basis)	