



Biocon Biologics™
Transforming Healthcare. Transforming Lives.

Global policy on Interaction with Healthcare Professional (HCP) and Healthcare Organization (HCO)

BIOCON BIOLOGICS LIMITED

POLICY DOCUMENT



Policy Title	Global policy on Interaction with Health Care Professional (HCP) and Healthcare Organization (HCO) [Policy]		
Scope/applicability	This Policy applies to all company employees of Biocon Biologics and business partners engaged to interact (directly or indirectly) with HCPs and/or HCOs across all jurisdictions.		
Purpose	To provide minimum standards of conduct to be undertaken Biocon Biologics employees and business partners in their interactions with HCPs/HCOs for the enhancement of healthcare and patient support.		
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1. Introduction and Purpose

The healthcare industry is one of the largest industries that impacts society and individuals equally. Therefore, it is necessary for Biocon Biologics, which is a part of this healthcare industry, to be responsible so as to ensure and reflect its commitment towards society by following and adhering to the highest ethical standards.

Biocon Biologics understands the importance of healthcare and its impact on an individual's life. As a healthcare products company, we conduct a wide range of promotional and non-promotional activities.

This Policy is formulated to align us with the highest ethical standards relating to the marketing, promotion, and sales of our products and to maintain the highest ethical standards in the wide range of activities we conduct.

This Policy is a reference tool. More stringent requirements may apply according to local laws, regulations and industry codes. All relevant and respective country specific policy, guidelines, documents and directives to be referred / followed for detailed guidance.

2. Principles and Values

Biocon Biologics is committed to following responsible, transparent, and ethical healthcare centric sales and marketing practices. We believe in building ethical relationships to help patients and healthcare professionals by developing and marketing medical products. We believe in providing and sharing accurate information regarding medical and scientific developments for the enhancement of healthcare and patient support.

Our vision is to be a global leader in Biologics delivering affordable access to innovative and inclusive healthcare solutions and transforming patients' lives.

Amongst other values as detailed in Biocon Code of Conduct, the Company advocates and reinforces on Integrity & Ethical behavior with zero-tolerance approach to any violations.

3. Applicability

This Policy applies to all employees of Biocon Biologics and business partners engaged to interact (directly or indirectly) with HCPs and/or HCOs across all jurisdictions.

4. Definitions

Terms	Definition
Advertisement	means and includes but is not limited to any verbal, written, pictorial and other descriptive matter including but not limited to commercials, newspapers, magazines, pamphlets, presentations, press releases, posters, promotional mails and text messages, electronic and digital media publications that are intended to promote the sale or use or supply or prescription/recommendation of a medicine/product.

Biocon Biologics/ Company/BBL	shall mean Biocon Biologics Limited and its subsidiaries.
Communication	means and includes any text, voice, audiovisual or image, mails, and emails both internal and external.
Company Organized Events	mean and include any event or activities whether planned/organized/executed by the company either in part or whole to meet legitimate and documented business needs to interact with HCPs or HCOs. For the purposes of this code it shall also include Educational events and promotional/non promotional events.
Company Representative	means and includes any member of company (promotional/sales or non-promotional/medical/scientific team) either engaged directly or indirectly by contracting with third party vendor who interacts and engages with HCPs/ HCOs/ pharmacies/ medical institutions/ hospitals/ healthcare facilities/ industry associations/ patient organizations with regard to Healthcare/ Medicinal Product. For the purposes of this code, the Company Representative shall also include Medical Representative.
Donations	means and includes monetary funds, equipment, company product or third party products used for charitable purposes, without intent or agreement to receive any benefit in exchange.
Digital Media/Electronic Media	means and includes the Internet, Websites, Television, Radio, Social Media and E-Commerce.
Educational Grants	mean and include funding or sharing of company/third party products to HCO for the sole purpose of supporting and enhancing Medical Education and Healthcare, without intent or agreement to receive any benefit in exchange
Medical/ Educational Grants	means funding due to an unsolicited request to support medical/scientific research, education, policy initiatives, and patient advocacy-related activities without intent or agreement to receive any benefit in exchange.
Entertainment	means and includes but is not limited to music & dancing arrangements or places where music and dancing are the primary attraction, theatre including movie theatres, sporting events, clubs and other leisure arrangements.
E&C team	Shall mean and include the members of Biocon Biologics Ethics & Compliance team.
Healthcare Organizations (HCOs).	means and include any legal entity or body, whether private or public, whether profit or nonprofit, that is a healthcare or medical/scientific association, such as a hospital, nursing, pharmacy, laboratory, clinic, research/educational institution, professional societies that have influence directly or indirectly on purchase, lease, administer, recommend and prescribe medical technologies and services. Patient Organizations are not part of HCOs
Healthcare Professional(s) (HCPs)	means and includes any person whether a government official or private person or representative of a public/private/government organization, clinical or non-clinical, such as nurses, technicians, laboratory scientists, doctors, researchers, procurement professionals, pharmacists and pharmacist assistants that in their professional capacities might directly or indirectly (influence) purchase, lease, administer, recommend and prescribe medical technologies and services.

Healthcare Products/Medical Products	mean and include medicines, medical equipment/devices, complimentary medicines, prescribed/non-prescribed drugs, and scheduled substances.
Hospitality	means and includes arrangements made in relation to providing meals, travel, refreshments, and accommodation.
Legitimate Business Purpose	A business requirement which is directly or indirectly related to the business operations of the Company and which does not interfere with the fundamental rights and freedoms of individuals.
Medical Affairs Team	means and includes all persons either engaged as full-time/part-time/temporary/contractual employees, trainees, interns, consultants and volunteers that are not directly involved in promotion or promotional activities and are engaged in scientific and administrative work.
Patient/Disease Awareness Campaign	means and includes an educational event organized by the company to provide information and create awareness amongst the patients or general public about healthcare topics and therapeutic areas.
Promotion	means and includes any and every activity undertaken for marketing or advertising of any healthcare product
Promotional Material	means and includes but is not limited to gifts, brand reminders, leaflets, booklets, advertorials, presentations or any other material used for the promotion of any product via any medium.
Sample	means and includes products provided free of charge to HCPs or HCOs either single use or multiple use to equip and familiarize HCPs or HCOs with the product.
Scholarships and Fellowships	mean and include educational grants primarily monetary in nature provided to HCOs to support medical education or training.
Third Party/Business Partner	means and includes any intermediaries, agents, franchisees, vendors, suppliers, contractors, or distributors who interact with HCPs or HCOs for the sale or promotion of any products/services of Biocon Biologics. For purposes of this code, any institution that organizes event except Biocon Biologics shall be construed as third party.
Third Party Organized Events	mean and include any event or activities whether planned/organized/executed by the third party either in part that is independent, educational and scientific organized to enhance scientific knowledge and support healthcare.
Beverages	Includes Alcoholic beverages and non-alcoholic beverages such as drinks and other potable liquids intended for human consumption, including beer, wine, soft drinks, fruit juices, etc.

5. Healthcare Professional (HCP) Interactions

Biocon Biologics, its Company Representatives and its Business Partners interact with Healthcare Professionals (HCP) in various settings for the purposes including but not limited to the exchange of scientific and educational information, promotion of company products and consulting. Below key principle & guidelines will help ensuring that our interactions with HCPs are conducted ethically to meet a legitimate business need and not for any actual or perceived improper, unethical, or illegal purpose.

Balanced and Truthful Statements: Statements about BBL products in all materials & communications must be balanced, truthful, consistent with the scientific evidence & leading medical practice. Materials & communication should not interfere HCP judgment and must not include unsupported medical assertion or claims.

Promotional Materials: Any promotional materials used while interacting with HCP must be reviewed & approved as per the Affiliate review process by the applicable legal and regulatory requirements.

No Off Label Promotion: All communication with respect to product must be consistent with the approved Labelling. No promotion of products which are not approved, cleared, or authorised by relevant regulatory authorities. Any queries, enquiries beyond approved labelling should be directed to Scientific or Medical/Clinical affairs team.

No Quid Pro-Quo arrangements with HCPs. Never communicate or appear to offer any payment or item of value in return for prescribing product or formulary placement.

6. Fees for Services:

BBL may obtain services from HCPs & other service providers to meet specific legitimate business needs for information, service, or advice. The rationale for the legitimate business need must be documented & retained. Appropriate frequency for the services in question should be considered in determining the business need. A non-exhaustive list of types of professional services includes Speaker programs, Advisory Boards, Market Research, Product related trainings organised by Biocon, Live case training like Preceptorships / Proctorships, Consulting services etc.

Selection of HCPs / Other Service Providers: HCPs / Service providers to be chosen based on the defined criteria such medical expertise, skills, knowledge & experience. Service providers selected must be qualified to perform the services for which they are selected. Service provider shouldn't be selected solely based on the past usage of BBL products or any future commitment to buy / recommend or prescribe BBL products.

Local Limits / Employer Rules & Approvals: While engaging service providers the business owners must consult and follow local rules, regulations as well as follow service provider employer's rules as communicated. While engaging Government Officials follow the applicable rules & limits of home country.

Professional Service Agreement (PSA): All service arrangements must be included in the PSA. The PSA must utilize templates approved by Legal for the purpose of such engagements that specify services to be provided, the basis of payment, the requirement for the HCP to inform their employer of the engagement (where required), and the services will be as per relevant laws. In case of service provider is an entity then individuals providing services must be identified in the agreement. PSA to be signed by both parties prior to performance of any service.

Compensation: Compensation for services must not exceed the Fair Market Value & the compensation may not be based on past, present or future volumes / value of business with the Service provider. Where expressly permitted by affiliate compensation may include reasonable hours for preparation & travel time. Payments to HCPs / HCO must be:

- Made only for services included within the scope of the written agreement and only after completion of the services.
- Directed to the HCP/HCO's primary place of business (or residence) and to a bank account in the HCP/HCO's country of residence. Payments must not be made to a charity or other unrelated third party on the HCP's behalf.
- They must not be made in cash or processed via associate Travel and Expenses claims (such as Concur)
- Properly tracked and transfer of value must be disclosed, as required by local laws, regulations, and industry codes.

Payment Method: Compensation under PSA must be paid in Cheque, Wire Transfer, Bank Transfer only.

Proof of Performance: Evidence that the service occurred / provided must be documented and maintained. Proof of performance may take in the form of minutes of meeting, attendee sign in sheets, presentation slides or any other deliverable as applicable basis country specific requirements.

Non- HCP Government Officials: If the business anticipates engaging with non-HCP government officials, HCPs that are government officials or entities owned by government officials as service providers, in such case E&C team should be consulted or affiliate guidelines on interaction with HCP need to be followed.

HCP not providing health care: HCP having special status or role with government who performs role other than health care, E&C Dept. need to be consulted before interacting with such HCP.

7. Market Research Studies (MRS)

Following procedure to be followed in addition to PSA arrangement and applies to Market Research programs or studies directed solely at researching the sales & marketing aspects of existing or potential BBL products whether conducted by BBL or through 3rd Parties.

Permitted Programs: Market research programs includes HCP surveys, patient surveys & product evaluation surveys conducted by BBL or by 3rd party on behalf of BBL. MRS must be designed to address a specific marketing need or question & shouldn't be used as a promotion or selling opportunity. All documentation regarding Market research activities to be retained by BBL / 3rd parties engaged in conducting MRS.

Participant Selection: Although some Market Research will require experience / familiarity with BBL products, participants must not be merely selected solely due to their known status as prescriber or user of BBL products.

Compensation: Compensation for HCP must be as per the approved FMS guidelines. For Non-HCP participants compensation must be reasonable & consistent with industry standards and the type of research conducted reflecting time & effort required. For Patients & or Consumer participants, payments in the form of cash equivalents & other items of value are permitted as far as they are modest in nature. Cash equivalents & item of value are not permitted for HCP participants.

Agreement Required: When BBL conducts Market Research BBL must have a signed agreement with each participant & when BBL uses 3rd party service provider to conduct Market Research agreement must be executed with 3rd parties in advance of MRS & 3rd party is responsible for obtaining participant agreements.

3PP Requirements: In case Market research conducted by 3rd party on behalf of BBL 3rd party compliance process to be adhered & followed.

8. Company Organised Events

BBL may organize Speaker Programs & other events of a scientific, educational, commercial, or professional nature to increase knowledge of BBL products or therapeutic areas and/or provide scientific, educational and/or professional information related to BBL products and/or therapeutical areas.

Selection of Participants: The participants selected must have a legitimate business reason for being present for the program (e.g., qualification, need for attending the training etc.)

Professional Services: If BBL is engaging any external speaker BBL must have a signed PSA with the stakeholders and compensation must be as per the approved FMV guidelines. Refer procedure on Fees to HCP for additional guidance.

Contents and Agenda: BBL organized programs must have a well-defined agendas. Content for such programs must comply with all applicable legal and regulatory requirements. Any collateral must be reviewed & approved in accordance with affiliate requirements and local rules & laws.

Appropriate Venue & Location: The location and venue for an BBL organized program must be appropriate for the nature of the program and conducive to the primary purpose of the meeting. Venues should be modest & reasonable. Such a meeting should be planned at in-country site unless:
(a) most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country; or
(b) given the location of the relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country.

Venues known primarily for gambling, entertainment, leisure, spa or sporting activities are not considered appropriate.

No compensation for passive time spent at Meeting. BBL may not compensate for the time spent by the attendees at an BBL organized meeting.

Virtual Programs: Unless otherwise specified the requirements of BBL organized events apply to virtual meeting also. Employees must select appropriate technologies & platforms and maintain sufficient control over access & sign-in. BBL may provide modest meals & refreshments. Delivery of meals & Beverages to participants or providing gift cards/ cash equivalents is prohibited. Delivery of beverages is prohibited.

9. Patient and Consumer Activities

Patient & Consumer Distinction: BBL should distinguish while interacting directly with the individual who is current or potential user of the product, patients under HCP care from those consumers who are able to choose product without HCP guidance or prescriptions. Special care is required with respect to products prescribed or used only during the treatment by an HCP, BBL must avoid interfering with HCPs judgement, decisions regarding the treatment or creating impression that BBL is steering patients to certain HCPs.

Patient Organizations: BBL should maintain complete transparency while interacting with Patient Organizations supporting the interests of the patient. BBL may collaborate with Patient Organizations or Patients with the primary objective of increasing awareness, knowledge & improve patient care. Collaboration with organizations should be such that the Organization maintains control over the content of their work & retains their independence. BBL may be involved in determining the content or selecting Speaker only if requested in writing by Organization & only if allowed local rules, regulations, policies, procedure and industry codes.

Support to Patient Organizations: Any financial or non-financial support to any organization must be documented in a written legal agreement in advance. BBL must not be the sole exclusive funder of a particular patient organization & the written agreement should not grant exclusive right to BBL in terms of supporting organization activities.

BBL Health Events / Patient Access Support: BBL health events (e.g., health camps, health screening) may be carried out & support patient access to health care (including BBL product) for the purpose of improving health outcomes. Such events may include provision of items, services & health management tools, kits to customer, patient, consumers & HCPs as well disease or product trainings educations or health improving services like counselling or nutrition support.

Type of Health events:

- **Health Camps / Health Screening:** Event with patient interaction under guidance of qualified HCP where a diagnostic test is conducted with use of equipment or consumables at a discounted or free of cost with support from BBL. Health events may conducted be inside the HCP clinic or outside the clinic.
- **Patient Awareness Activities:** Event where patients are educated about a particular disease or dissemination of information about the disease.
- Patient Support Programs / Patient Access Support.

BBL Organized Health Events: When screening events are organized by BBL a qualified HCP must be engaged to provide health screening services in accordance with the procedure on Professional Service Agreement / Fees. BBL employees may not perform any tests on patients but may provide general support for the event related use of products. Participants at BBL organized event must sign an informed consent prior to any health screening.

In case of events organized by 3rd party informed Patient consent should be collected by 3rd party. Data privacy laws will be applicable for any patient data collected.

Product for Health Events: Products may be provided as a part of a health fair or screening event with appropriate HCP supervision & decision making with respect to any prescription product usage. Any product provided free of charge shall be in line with the procedures on providing Product at No Charge or procedure on Charitable Contributions.

Compensation of Service Providers: Patient & Consumer participant testimonials should be reasonably compensated with cash or cash equivalents in exchange for providing services. Compensation should be consistent with industry standards for services provided. HCP Providing services may be compensated in line with procedures laid down on Professional Service Agreements.

Personal Information: Any personal patient information collected in the course of business needs to be protected & handled in line with procedure mentioned in affiliate rules and applicable Data Privacy laws.

Additional Affiliate rules, procedures & requirements and applicable country specific laws to be followed while conducting above-mentioned events.

10. Support of Third-Party Programs

a. Direct Sponsorships: Support for attending Educational Conferences

BBL may provide direct sponsorship for HCPs & other stakeholders to attend 3rd Party Programs including educational, scientific and public policy conferences, symposia, workshops, seminars & similar meetings. The objective of sponsorship is to advance science and or improve health outcomes and patient care.

Selection Criteria: Where permitted by local laws, regulations BBL may select the participant for direct sponsorship having appropriate qualifications, experience & legitimate need for training / education. Selection criteria must be aligned with the permitted purpose of the support.

Advance Confirmation: BBL's support of stakeholder attendance at a 3rd Party Program must be confirmed in advance in a document signed by BBL & stakeholder.

Number of Sponsored Stakeholders: The number of stakeholders sponsored for 3rd party programs should be reasonable. In person attendance of 3rd Party program outside home country should be once in a year only.

Local Limits / Employer Rules & Approvals: When providing Direct sponsorships to stakeholder's employees must consult & follow any affiliate requirements as well as any rules of the stakeholder's employer communicated to BBL. BBL employees must ensure that they follow the most restrictive monetary limits applicable & procedural requirement imposed by local law, trade association and or recipient's employer. In the case of any engagement Government HCP/Organization follow affiliate requirements.

Appropriate events: Decision to provide sponsorship must be based on merits of the event, relevance to attendees practice & BBL areas of interest, strength of agenda, duration of program and venue or

location of the scientific program. The attendees should spend the bulk of their time on scientific, training & educational content. Local regulations, procedure & industry codes to be followed.

Permitted Support: Financial support towards Direct sponsorship program must be limited to registration fees, reasonable travel & accommodation & modest meals, refreshment associated with attending the 3rd Party program. No compensation for time spent at 3rd Party event by attendee.

b. Commercial Sponsorships: Support of 3rd Party Programs

BBL may provide financial support or funding to organizations, associations or entities holding independent programs, conferences or meetings typically involving educational scientific, public policy topics that have the purpose of advancing science & improving health outcomes.

Commercial sponsorships are primarily promotional in nature & include display of Biocon's logo, brand/product name, booth space / stall, satellite symposia time slots, and any other promotional commitment.

In case we pay for booth / stall space or to have product names / logos displayed at 3rd Party program the Product & brand promotion procedure will also apply. In case we pay for training or educational programs to attendees at 3rd party event e.g., Satellite Symposia then BBL Organized Program procedure will apply.

Permitted Recipients: Commercial sponsorships must not be provided to any individual.

Selection of Attendees: BBL may not be involved in selection of attendees for Commercial sponsorships however may send its own employees & if permitted by affiliate procedure, local applicable laws, regulation & industry code directly support individual HCP attendance in accordance with procedure on Direct Sponsorship.

Documentation: All commercial sponsorships must be documented in advance with clearly identifying the recipient organization, value of sponsorship, promotional opportunities, event description etc.

Appropriate events: Decision to provide commercial sponsorship must be based on merits of the program /event, relevance to BBL areas of interest, strength of agenda, duration of program and venue or location of the scientific program, budget & other similar factors.

No Control of Content, Faculty & Materials: BBL must not have any control over the faculty selection, educational methods, materials in connection with Commercial sponsorships. In case of any direct / indirect control BBL organized program procedure to be followed.

Payment Method: Payment must be made in the name of the recipient organization through a Bank cheque / Wire Transfer. No payment shall be made to any Individual. Cash or Cash equivalents are not permissible unless explicitly permitted by affiliate policies, procedures & laws.

c. Educational, Research and Medical Grants: Educational, Research and Medical Grants refers to BBLs provision of financial / product support for medical education programs to training institutions, healthcare institutions, professional societies or similar organizations for educational purposes.

Educational Grant may be provided for variety of purposes consistent with local laws regulations and industry codes Eg., Indirect sponsorships, fellowships, and/or Scholarships programs related to supporting public awareness and or educating patient caregivers or general public about healthcare topics.

Grants Permitted: BBL may provide educational grants to training institutions, HCI, professional societies or similar organizations involved in medical or scientific education. Educational grants must be used for legitimate purposes. The primary purpose of the grant is to advance science, medical education, and improve patient health outcomes.

No Funding or selection of Individuals: BBL must not select or provide inputs on individuals selected to receive the support. Any selection of the individual beneficiaries must be made by the Grant recipients or the organizations that provide the education. BBL must not be involved in reimbursing any individual expenses in connection with an Education Grant.

Documentation: All Educational Grants must be documented in advance clearly identifying the educational purpose and value of educational grants.

Payment Method: Payment must be made in the name of the recipient organization through a Bank cheque / Wire Transfer. No payment shall be made to any Individual. Cash or Cash equivalents are not permissible unless explicitly permitted by affiliate policies, procedures & laws.

11. Accommodations, Travels and Meals

a. Modest Meals & Refreshments

BBL may provide/pay occasional meals & refreshments modest in nature & cost as per local standards. Meals & refreshments in connection with legitimate educational & business purposes permitted under these & local procedures (e.g., business meeting with customer, BBL organized programs, advisory board, site visit).

Legitimate Business Interest: Meals & refreshments to be provided to attendees who have legitimate business interest in educational / business discussion.

No Guest: BBL may not provide meals & refreshments to guests, spouses or family members of stakeholders who do not have an independent business relationship with BBL. Attendees must have independent need to participate in the education or business discussion with which the meal or refreshment is associated.

Appropriate Venue: All meals & refreshments must be provided at business appropriate venues. Venues primarily known for gambling, entertainment, spa / sporting activities are not appropriate.

Beverages Subject to any more affiliate requirements, beverages may be provided at business meetings when appropriate to the business environment or circumstances. Beverages are incidental to business discussions and not provided as a form of entertainment.

Cost Limits: Local Affiliate limits to be adhered along with procedure on Cross Border Interactions

Itemized Receipts & Reports: All expenses must be supported by itemized receipts or invoices, or other documents. Expense report to capture Name of venue, stakeholder, HCP attendees & business purposes for the event.

Virtual Meetings: Modest meals can be provided to stakeholders in connection with remote/virtual educational events / business meetings. Delivery of meals / gift cards / alcohol at residence are prohibited.

b. Reasonable Travel & Accommodation

BBL may provide reasonable travel & accommodation in connection with appropriate business purposes permitted under these & other local procedures.

Local Limits / Employer Rules & Approvals: Stake holder travel & accommodation may only be paid by BBL to the extent expressly permitted by Affiliate requirements as well as any rules of the Stakeholder employer communicated to BBL.

No Compensation for Time Spent: BBL may not compensate any Stakeholders for time spent / income foregone while away from work.

No Travel expenses for Routine Meetings: BBL may not compensate travel expenses associated with routine business meetings which generally occur at Stakeholders place or BBL premises.

Travel Arrangements: Wherever possible all travel arrangements must be routed through BBL authorized agents / suppliers. An itemized invoice must be obtained for all travel & accommodation expenses.

Modest Travel & Hotel Accommodation: All travel and accommodation must be reasonable & modest. Flight time of less than 5 hours (1 way) must be booked in economy class. Excessively luxurious hotels associated with gambling, entertainment, spa, sports resort must be avoided & accommodation should be modest. 1st Class journey not allowed.

No Guest: Funding travel and accommodation of stakeholder guests is not allowed.

Duration of Stay: Travel and accommodation of the stakeholder should be such that no arrival should be greater than 1 day from the start date of event & no departure should be greater than 1 day from date of conclusion of event

12. Charitable donations

BBL may provide Charitable Contribution of BBL product, non BBL product or equipment or funding to organization or entities for charitable purposes such as improving delivery of healthcare, increasing patient access to health care technology & humanitarian assistance. Charitable contributions are provided to benefit society & advance the well-being of communities around the world.

No Political or Religious Purpose: Charitable contributions may not be provided to support political organizations, lobbying efforts or religious organizations unless it is to support their non-religious charitable programs. Consult Government Affairs for appropriate process regarding lobbying or political organization contributions.

Contribution requested by HCPs or Government Officials: If an HCP or Government Official requests for contribution to charitable organizations / institutions prior consultation with Ethics & Compliance team is required. Charitable contribution should not be in lieu of paying professional fees to HCP / Government Official.

Permitted Recipients: Contribution can be made to organizations engaged in genuine charitable activities such as delivery of health care, increasing patient access to healthcare technology & humanitarian assistance. Charitable Contribution cannot be provided individual HCPs / Government official.

Documentation: Written documentation / Agreement must be made in advance between BBL & recipient of Charitable contribution clearly identifying organization, entity, amount of value, nature of contribution & the purpose of contribution. The agreement/documentation should clearly mention that BBL is not providing the contribution as an inducement or reward for past or future business. If any products are provided the agreement/documentation should clearly indicate that the product should not be billed, charged, or sold.

Monetary Contributions: All monetary contributions must be approved by Ethics & Compliance & should be in line with Affiliate requirements. All monetary payments should be made through cheque / wire transfer to recipient organization or entities. Cash & cash equivalents are not permissible form for charitable contribution.

Product Contributions: The value of product contributed must be reasonable & consistent with the specified purpose & should adhere Affiliate procedures & local rules & regulations. Products donated must comply with quality & regulatory requirements including tracking, shelf life and packaging for intended destinations.

No charitable contribution to support educational event & such contributions should be in accordance with procedure on Direct Sponsorship.

3rd Party Intermediaries: This procedure applies to contributions handled by BBL directly or indirectly through any 3rd party

13. **No Charge Product (Samples, Single Use / Multiple Use, Demonstration/Training, Validation, Verification)**

General Principle: BBL may provide products to HCPs, Customers, Patients & Others Free of Charge for legitimate business needs / purposes. While there are legitimate reasons for providing a No Charge Product, the provision also presents risk & could be used as an incentive or for other improper business purposes.

Except Physician Samples all Free of Charge products provided must be pre-approved & acknowledgment note of receipt of product / feedback report must be obtained from the recipient in an approved format. Wherever the free of charge products are requested by HCP then written request from HCP/HCI is required.

BBL may provide No charge products as product samples, single use / multiple use evaluation product, demonstration / training, validation, verification, and any other legitimate business purpose and should be in line with local laws, regulations & industry codes.

Labelling or Identification: Product samples, Single Use/Multiple use evaluation products, Demonstration product, Products for HCPs training, Product for validation/verification may not be sold/traded by the recipient to any 3rd party.

Product samples, Single Use/Multiple use evaluation products, should labelled / identified as Product samples, Single Use/Multiple use evaluation products Not for Sale. Demonstration Product / Product for HCP training, Products for validation & verification should be identified separately.

The identification language may appear on the Product, Product packaging or any other appropriate documentation accompanying the product.

Reasonable Quantities: All provided product samples, single use/multiple use evaluation products, demonstration product, products for HCPs training, product for validation/verification must be reasonable in nature & should be based on the intended usage & duration. Quantities unused or unutilized should be returned to BBL or destroyed accordingly.

Tracking: Product samples, Single use / Multiple use evaluation product should be tracked. Tracking can be manual or electronic capturing the details of Products, Quantities provided, details of recipient, Additional affiliate requirement & procedures to be followed.

No Charge Program which does not adhere to these program & procedure may only be implemented with prior Ethics & Compliance approval.

This provision applies whether we manufacture or distribute the products.

If the product is provided for charitable purpose procedure on Charitable Contributions to be adhered.

If the product is provided for educational purposes procedure on Commercial sponsorship: Support to 3rd party programs & Educational Grants to be followed.

If the product is provided in connection with Health Economics or Market Access Studies, the procedure on Scientific Activities should be adhered to.

Free of charge products provided under or in connection with Volume, Bulk purchasing arrangements, Tender arrangement procedure on Commercial transaction to be followed.

Patient Assistance Program: No Charge product is provided to patients under compassionate grounds and who are undergoing medical care & who may not afford the therapy / treatment cost. Patients must have a valid prescription along with HCP request letter for availing benefit under Patient Assistance Program.

14. Items to HCP (Brand Reminder, Item of Medical Utilities and Cultural Courtesies)

BBL doesn't offer / give any gifts. BBL may however provide brand reminder, cultural courtesies or items of medical utilities under appropriate circumstance & in accordance with laws and procedure. This applies both to items supplied by BBL or to 3rd party acting on behalf of BBL.

Brand Reminder (BR): A Brand reminder is an item of nominal value & with BBL / BBL product branding provided by or on behalf of Biocon to stakeholders / organization and is solely intended as promotional reminder of BBL products.

Cultural Courtesy (CC): A cultural courtesy is a greeting card or perishable item with nominal value that is provided by BBL or on behalf of BBL to stakeholders or organization and is intended to recognize national or religious holiday or a personal milestone.

Medical Utility (MU): An item provided by BBL or on behalf of BBL to stakeholder, organization which has genuine educational function or is intended to benefit patient care. Items must have a modest reasonable value & shouldn't be provided for personal use.

Local Limits / Employer Rules & Approvals: To the extent expressly permitted by affiliate requirements as well as any rules of the stakeholder employer communicated to BBL, Biocon may provide stakeholders with brand reminders, cultural courtesies or items of medical utility. Biocon employees must ensure that they follow the most restrictive monetary limits applicable, and any procedural requirement imposed by relevant local law, trade association and / or stakeholder employer. In the case of any interaction with government officials, HCPs follow and apply the affiliate rules & limits.

Prohibited Items: Cash & cash equivalents, gift cards, tobacco products are never permissible as brand reminders, items of medical utilities, cultural courtesies.

Centrally Purchased: All Approved Brand reminders & medical utility items must be centrally purchased by the affiliate & supported by appropriate Invoices.

Tracking Mechanism: All items of medical utilities, brand reminders & cultural courtesies need to be tracked and reported.

15. Cross Border HCP Interaction

When engaging as HCP to provide services pursuant to a PSA & the HCP home country is not the same as the country seeking the services refer guidance from Ethics & Compliance team. This engagement is generally complex & poses higher compliance risk please contact affiliate Ethics & Compliance team.

Refer guidance on country specific requirement when providing something of value, including meals, transport & stay to HCP in Cross Border Interaction & consult with affiliate Ethics & Compliance team.

16. Interaction with Stockiest, Pharmacist

Biocon Biologics may interact with pharmacist or stockiest for product discussions. The purpose of these interaction must be legitimate with primary objective to educate pharmacists / stockiest on product use, efficacy, dosage, safety. All such meetings must be documented & only preapproved materials should be used.

17. Data Privacy

Any personal information collected with respect to patient, 3rd Party, Healthcare Professionals during any engagement / interaction, should be critically protected in line with applicable Data Protection / Privacy Laws.

18. Transparency Reporting

Biocon Biologics believes and reaffirms the importance of transparent interactions with the HCPS, scientific experts, HCOs, and others. These interactions and information relating to them including but not limited to payments, transfer of value, items of value and gifts should be reported to the concerned authority as required by internal mechanisms and applicable local laws.

19. Clinical Research, Investigator Sponsored / Investigator Initiated Studies.

Biocon Biologics may engage HCPs/HCOs/Educational Institutions for assistance in clinical research. Validator to provide insight on stage of clinical trial (including post market assessment studies) such as participation in trials, undertaking preliminary research etc. The purpose of this research is to enhance scientific acumen & benefit patient. Clinical & scientific activities must be conducted, supported, and approved by those qualified (R&D, Clinical, Medical, Regulatory) to determine the scientific & clinical merit of such activities.

20. Training and awareness

The Company's Legal- Ethics & Compliance Department endeavors to provide appropriate training in relation to this Policy.

21. Deviation

Any deviation / exception shall be reviewed and approved by the Ethics & Compliance Department.

22. Compliance Contacts

For general inquiries or questions related to this Policy please feel free to reach out to Ethics & Compliance at GEC.biologics@biocon.com