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WELCOME TO BSV Compliance Program

Rev.20FEB25

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Distributor Compliance Training

- Audience: This course is intended for all employees of Third-Party Distributors who interact or conduct business on behalf of Bharat Serum & Vaccines (BSV) with Health Care Professionals and/or Government Officials





Objective

GAIN A COMPREHENSIVE UNDERSTANDING OF
THE COMPLIANCE OBLIGATIONS OF BSV AND
THIRD PARTY DISTRIBUTORS

Context

BSV is a subsidiary of Mankind Pharma Limited and has wholly owned subsidiaries in Philippines, Malaysia, Germany and US.

Hence, the following acts apply to BSV-

- Foreign Corrupt Practices Act
- UK Bribery Act

Indian Regulatory Laws such as the Prevention of Corruption Act also applies to BSV

- Almost, all countries around the world, have:
 - Laws containing anti bribery and anti-corruption provisions
 - Laws prohibiting bribery in private sector

Global Anti- Bribery and Anti- Corruption Regulations

ANTI-BRIBERY AND ANTI-CORRUPTION PROVISIONS
FOR BOTH PUBLIC AND PRIVATE SECTORS

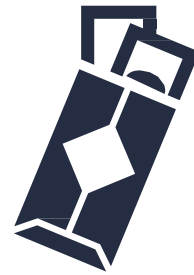


Key Compliance Considerations



Bribery and Inducements

Distributors/Stockists must not offer or accept bribes or other illegal inducements in any business or government relationships



Value of Benefits

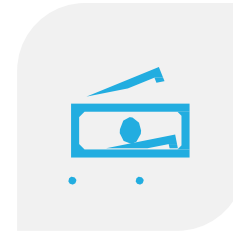
Includes cash, reimbursements, gifts, hosted travel, or any other benefit offered to influence decision-making

Applies to all actions intended to further a corrupt payment, not just the payment itself

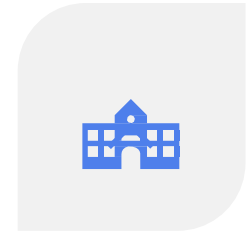
HCP Interactions



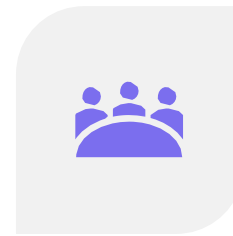
Services should be documented in a written agreement, detailing compensation at fair market value



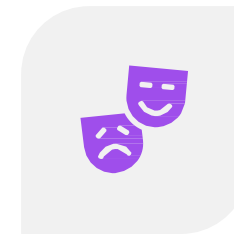
Performance of services must be recorded before payments are made



Travel, lodging, and meals for hcps must be reasonable and not include non-service-related individuals or side trips



Meeting locations should be modest, and it must be suitable for business or scientific exchange



No entertainment or recreation is allowed for HCPs

Gifts to HCPs & Government Officials are Prohibited



No gifts in any kind should be provided for the personal benefit of any healthcare professional OR their immediate or extended family members, either directly or indirectly



Brand Reminders may be provided to the HCPs.



Government Officials are prohibited from soliciting or accepting gifts



However, Brand Reminders are not GIFTS



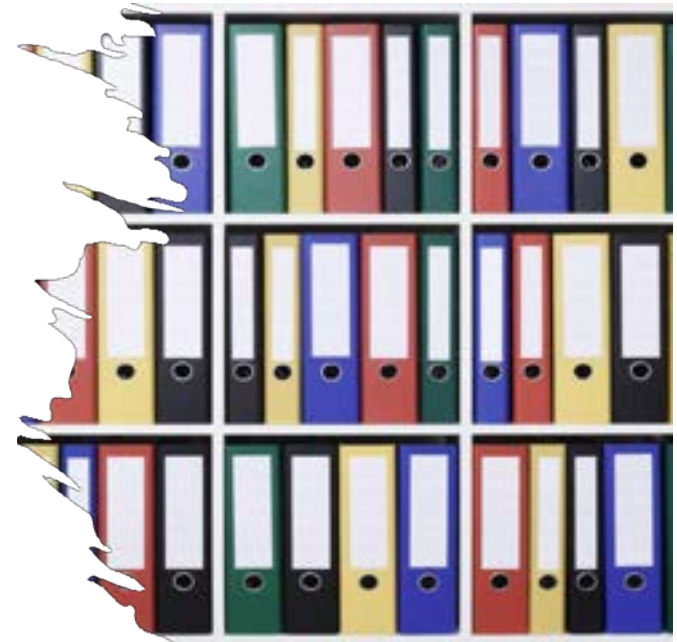
Brand Reminders

- Brand Reminders must be
 - Educational or scientific in value
 - Beneficial to patients and relevant to the HCP's practice



Documentation Requirements

- All invoices, debit notes, and documents must be
 - Clear, with sufficient detail
 - Transparent to enable proper auditing



Important Undertakings

- Distributors must communicate any changes in their legal status, control, constitution, or authorized signatories to BSV with supporting documents
- Products must always be insured
- No transfer of rights or benefits without BSV's prior written consent
- Compliance with all laws & local regulations (including obtaining requisite Licenses) and BSV mandated storage requirements (e.g. temperature maintenance at distribution facilities) is essential
- BSV's employees/representatives may verify stock levels, inspect temperature control equipment, conduct quality audits, and check the validity of licenses



Tenders & Procurement Guidelines

- Distributors must
 - Inform BSV about participation in tender
 - Follow local tender regulations
 - Share only officially approved information (including tender award)
 - Maintain confidentiality while ensuring transparency



Unacceptable Practices



Collusion or manipulation in public procurement



Offering unapproved products/services or providing unofficial materials

Use of sub-distributors or third-party contractors

BSV expects its Distributors to inform BSV of any use, or planned use, of sub-distributors or similar third-party contractors, providing their details and explaining how the Distributor intends to utilize these sub-distributors or third-party contractors for distribution and marketing purposes



Acceptable Practices

- Notification: Inform BSV about the involvement of sub-distributors or similar third-party contractors
- Screening: Conduct thorough vetting of your partners
- Written Agreements: Ensure all agreements with sub-distributors include compliance and audit clauses
- Compliance Assurance: Confirm that sub-distributors adhere to the same compliance standards and obligations as outlined in your agreement with BSV

Unacceptable Practices

- Conflicts of Interest: Do not engage sub-distributors or third-party contractors who have a vested interest with public officials to gain undue favors
- Recommendations: Avoid hiring sub-distributors solely based on recommendations from customer
- Risk Ignorance: Do not overlook potential risks or red flags with such parties
- Unethical Conduct: Do not permit sub-distributors or third-party contractors to act unethically or breach the BSV Code of Conduct

Anti-Competitive Practices

Avoid all types of anti-competitive activity in your business including

- price fixing
- bid rigging
- sharing markets or customers
- sharing commercially sensitive information



Operate the business in accordance with both the written legal and unwritten fair competition rules, while minimizing the risk of legal infringements.

Acceptable Practices

- ❑ Independent Collaboration: Collaborate with customers, such as sub-distributors, at arm's length
- ❑ Non-Binding Price Recommendations: You may provide sub-distributors with a non-binding price recommendation, as long as no pressure or incentives are used to enforce the price
- ❑ Independent Decision-Making: Make independent decisions regarding tender participation and avoid sharing these decisions with sub-distributors or competitors

Unacceptable Practices

- ❑ Anti-Competitive Agreements: Do not engage in agreements with competitors, customers, or suppliers that could be considered anti-competitive
- ❑ Exchange of Sensitive Information: Do not share commercially sensitive information with competitors
- ❑ Control Over Sub-Distributors: Avoid exercising control or influence over sub-distributors' business activities, including imposing resale price maintenance, exclusive purchasing/supply obligations, territorial or customer restrictions, export bans, or online sales restrictions
- ❑ Abuse of Dominance: Do not abuse any dominant market position through exclusivity clauses, loyalty rebates, or discriminatory practices

Key Takeaways



Strict compliance with BSV agreements



Adherence to the local country ABAC laws



Ensure clear documentation and transparency in all transaction



THANK YOU !
