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Developing and Implementing an International Pharmaceutical Compliance Program

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ENFORCEMENT CLIMATE – WORLD OVERVIEW

Greater Scrutiny in the US

- **Numerous publicized investigations in US of various pharma companies regarding marketing and other activities.**

Enforcement Environment in Europe

- **To Date: Somewhat less aggressive than US, however note recent investigations in Germany and Italy.**
- **Unreasonable to think same concerns expressed by US regulators not shared by regulators worldwide.**
- **Unreasonable to think similar enforcement actions will not be taken.**

ENFORCEMENT CLIMATE – WORLD OVERVIEW

- **Government deficits and increasing healthcare costs everywhere spur heightened interest in controlling drug costs and utilization.**
- **Significant focus by all regulators on "payments" to physicians alleged or perceived to induce prescriptions or to curry favor.**
  - **"Payment" is cash or any thing of value.**
  - **US FCPA and Local Civil Servant/Bribery Law implications.**

Common Types of "Payments"

1. Entertainment, Gifts and Promotional Items
2. Medical/Scientific symposia
3. Scientific Studies: Registration and Post-Registration
4. Samples
5. Consultant Agreements; Misc. Services
6. Grants/Donations/Contributions

"Payments" – Potential Vulnerability

- Symposia, congresses, advisory boards, consulting agreements, speakers meetings, etc.
  - Potentially problematic if selection is based on actual or potential prescribing habits vs. expertise.
  - Payments made for little or no value provided.
  - Can number of participants/ consultants be justified?

"Payments" – Potential Vulnerability

- **Grants/Donations/Contributions**
  - → **To whom and for what purpose?**
  - → **Unsolicited or solicited**
  - → **Need to be transparent and not related to sales or promise of sales.**
- **Opinion Leader Programs**
  - → **Scientifically based or promotionally based?**
- **Samples**
  - → **Must be tracked and controlled; comply with local regs.**

"Payments" – Minimize Vulnerability

General Guidelines

1. Be Transparent.
2. Comply with local regulations and Company policies.
3. Any services retained must be necessary, lawful work requested by and provided to the Company.
4. The purpose and amount of payments must be supported by adequate documentation proving that services were received, used and fair value paid (FMV Analysis).
5. All payments made by Finance, via check or electric bank transfer. No cash payments allowed.
6. If Government employee, conduct FCPA Analysis.

Sample Provisions – Minimize Vulnerability

- **The compensation Company will pay you for the services set forth in this Agreement is <AMOUNT> Dollars ($XXXX), which the parties agree is fair market value for the services to be provided. In addition, Company shall reimburse your reasonable and documented out-of-pocket expenses incurred in connection with the services you provide hereunder in accordance with the attached Reimbursement Policy.**

Sample Provisions – Minimize Vulnerability

You confirm that as of the date of this Agreement:

- **(i) you have the authority to execute this Agreement and are under no legal restriction which would prevent, impair or otherwise affect your ability or legal right to enter into this Agreement (including all applicable laws, regulations and employer policies);**
- **(ii) payment of fees to you hereunder is permissible under all laws, regulations and rules applicable to you; and**
- **(iii) you are not a party to any agreement that is inconsistent with this Agreement and/or your performance hereunder, or that will in any way conflict with your ability to fulfill the terms of this Agreement, and that you will not enter into any such agreement during the term of this Agreement.**

Sample Provisions – Minimize Vulnerability

- **You shall be personally responsible for declaring this Agreement to the Conseil Departemental de l'Ordre des Medecins with whom you are registered in accordance with Article L 4113-9 of the French Code of Public Health….**
- **You agree to comply with the laws, regulations, codes, guidelines and rules applicable in the province of Quebec [or other applicable province] and in Canada, including the ethical rules applicable to the profession in your province of residence, as well as the internal rules and guidelines of the University or Hospital where you work and/or of any other employer….**

Sample Provisions – Minimize Vulnerability

- **You agree to comply with applicable laws, regulations and rules (including the internal rules and guidelines of the University or Hospital where you work and/or any other employer), as well as with the ethical rules applicable to the medical profession in your country of residence.**
- **You also agree that you will make all required disclosures and obtain all approvals with respect to your engagement hereunder as required by applicable laws, regulations and rules, including without limitation any required notification to the relevant ethics committee, government agency or your employer.**

Sample Provisions – Minimize Vulnerability

- **You shall neither disclose to Company nor induce Company to use any secret or confidential information or material belonging to others, including former employers or companies which have retained you as a consultant.**
- **You represent and warrant that you have not been excluded or barred from the practice of medicine by any government or professional agency in any country where you have practiced medicine.**
- **You agree that Company may identify you as having performed the services pursuant to this Agreement in communications to its affiliates or to third parties, including transmission of your personal data to parties in the US.**

Consent/Notice - Minimize Vulnerability

- Some local laws require prior notice and/or consent before "payment" can be made to physicians (e.g., Italy, France, Germany, etc.)
- Notice and/or consent process may need to be initiated 2 – 3 months before "payment" or event occurs.
- Consider both local and EU positions (e.g., EMEA, COPM, etc.).
  - → EMEA Code of Conduct (12/3/99; EMEA/D/37674/99)

Risk of Off-Label Promotion

- **Off-Label promotion violates EU, US Regulatory Law**
  - **Direct or Indirect**
- **<u>Direct</u>:**
  - **Affirmatively promoting unapproved indication.**
  - **Must have rigorous system to vet and approve promotional materials in accordance with local law.**
- **<u>Indirect</u>:**
  - **Supporting off-label use can be alleged through supported or sponsored studies or clinical trials, Symposia, Speaker's Program, Advisory Committees, Preceptorships.**

CONCLUSION

- **Heightened enforcement activity can be expected as budgetary issues tighten.**
- **Key is Transparency and Documentation.**
- **Know and Comply with Local Laws and Company Policy.**