



Arrangements with Consultants and Fair Market Value (FMV)

The Medical Device Code of Ethical Marketing and Business Practice

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Scenario:

Company X engages with Doctor Z to deliver a service. Company X are offering Doctor Z a Fair Market Value amount but Doctor Z only agrees to take R0.00. Doctor Z is of the opinion that no Agreement needs to be signed. Company X wants to confirm if it is complying with the Code?

SAMED Code – Chapter 5: Arrangements with Consultants

- Five parts: General principles, Criteria for genuine consulting arrangements, Remuneration and fair market value, and Payments;
- Remuneration and fair market value addresses:
 - ✓ Disclosure and transparency of Fair market value (FMV) definition;
 - ✓ Commercial reasonableness;
 - ✓ Valuation elements;
 - ✓ The valuation risk assessment;
 - ✓ Assessing FMV for HCPs and Key Opinion Leaders (KOLs).

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- Focus on the following criteria:
 - Legitimate and specific identified need;
 - Qualifications, expertise and experience to address the identified need.
 - Written agreement and signed by the parties in advance;
 - The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided;
 - Member companies must maintain records of the services.
- Compensation earned by a HCP in his/her practice may not be directly comparable to the compensation associated with providing services to a member company.

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- Compensation should be based on an objective and consistent methodology including:
 - Specific requirements of the company, product group or department engaging with the HCP;
 - The specific services required;
 - The HCP's experience and expertise;
 - The time requirements for the engagement;
 - The HCP's clinical specialty.
- Very important: Transparency and disclosure are key.

Conclusion:

- **What is meant by fair market value (FMV) in the context of consulting arrangements?**
 - Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.
- **How should Member Companies determine FMV for a service?**
 - A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take into account the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company.