



# Lodging a Complaint and Enforcement Process: Part 2 of the Code

**SAMED**

south african medical device industry association

advancing **innovation** responsibly



# Approach to enforcement

- Complaint-driven: companies, HCPs, associations, public can lodge complaints (in writing, no anonymous complaints considered)
- No complaint handling fee for HCPs, HCOs, public
- Companies: complaint handling fee R2500 incl vat
- No investigation or hearing without a complaint
- Independent administrative justice process – starts with effort for conciliation
- Investigation is conducted by an independent investigator
- Hearings are conducted by ethics committee
- Legal representation only in particularly complex matters
- Schedule of sanctions as part of Code

# Response to alleged breaches of the Code

EO/Secretariat receives complaint, asks Respondent to respond and Complainant to reply. Sends documents to Independent Investigator



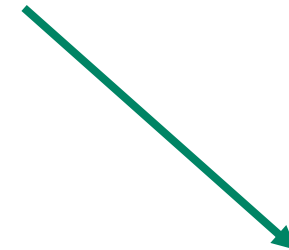
Independent Investigator conducts investigation and produces report. May recommend conciliation



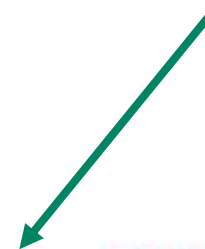
Ethics Committee receives Investigator's report. Adjudicates cases with merit through formal hearing



Complainant, Respondent and possibly witnesses and experts participate in hearing. Committee delivers finding, imposes penalties where applicable



Secretariat facilitates conciliation. Some matters settled. Others referred back to adjudication



# Examples of sanctions and fines

Minor	Moderate	Severe
<p>Immediate suspension of activity Company to issue a corrective statement, as determined by ethics committee, including target audience Written reprimand to company by SAMED Notify HCP of breach, if relevant Fines: R 10000-R50000</p>	<p>Immediate suspension of activity. Company to issue a corrective statement, as determined by ethics committee, including target audience Written reprimand to company by SAMED Notify HCP of breach, if relevant Fines: R 100000-R200000</p>	<p>Immediate suspension of activity Written reprimand to company by SAMED Company to issue a corrective letter to healthcare professionals/public, as determined by ethics committee Fines: R200000 – R300000</p>