

## Summary & outcomes of SAMED Medical Device Code hotline\* complaints May 2021

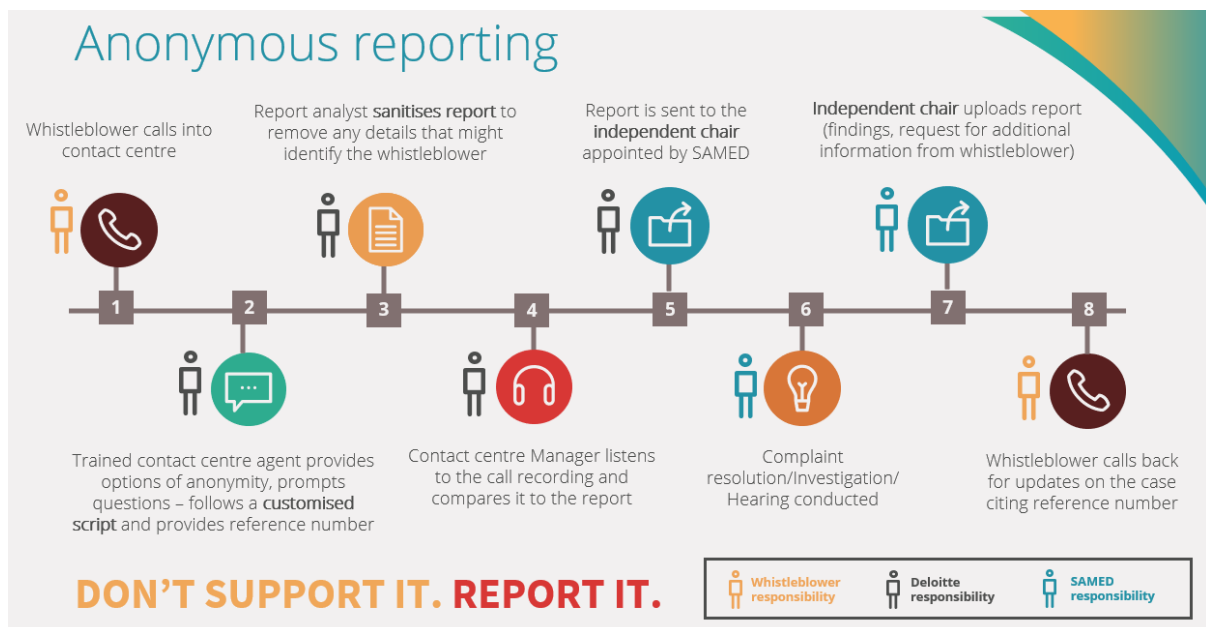
**DON'T SUPPORT IT. REPORT IT.**

Report transgressions of the Medical Device Code

Freecall 24/7 hotline **0800 000 468**

SAMED's whistleblowing hotline was established in August 2019 to provide an **anonymous** platform for anyone to report transgressions of the Medical Device Code of Ethical Marketing and Business Practice (the Code) by signatories to the Code (SAMED members).

The whistleblowing hotline allows for callers to remain completely anonymous when making a report.



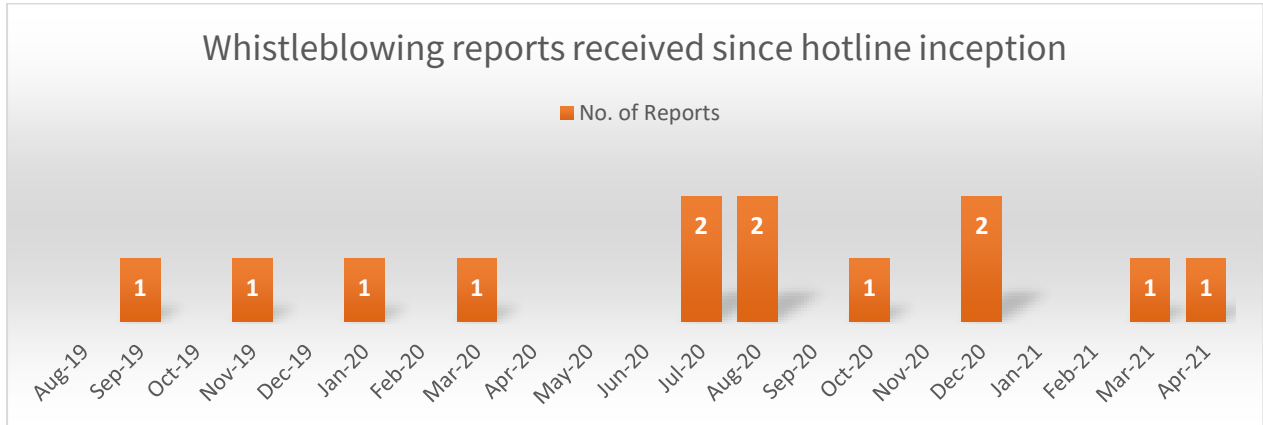
The independent hotline is managed by Deloitte. The Deloitte call centre captures the complaint and produces a sanitised report for the independent chair to review.

The independent chair decides on a course of action inter alia - reporting the matter to a relevant authority, conciliation, mediation, further investigation, a hearing which may result in sanctions.

The independent ethics chair will report on actions taken and this is logged on the Deloitte hotline system against the complaint reference.

As neither the independent ethics chair, nor Deloitte will have personal information from a completely anonymous complainant, it is essential that they call back after 14 days to check on

the status of their complaint. This allows the complainant to receive feedback and/or provide further information or evidence if such is required to progress the complaint.



Below, we provide a summary of the complaints received to date as well as their status/outcome. SAMED keeps a repository of code complaints and outcomes to establish a database of historical cases. We have made this publicly available in the interest of transparency.

Complaint	Summary of the complaint	Complaint outcome
1	The complaint was regarding a company trading without a medical device quality management system.	The matter was referred to the relevant authorities - South African Health Products Regulatory Authority (SAHPRA).
2	The complaint was regarding tender irregularities.	The matter was referred to the relevant authority i.e. the HAWKS/SAPS.
3	The complaint was regarding unethical marketing and sales practices by the sale staff of the Respondent. The complainant indicated the respondent is not transparent in their marketing ventures, provide false information to promote their product and interrupt training sessions for sales calls. The Respondent denied the allegations made by the complainant. The complainant was requested to contact the Independent Chair to provide further information or evidence which they failed to do.	No further investigation due to a lack of further information provided.
4	The complaint was regarding altering of manufactured products as supplied by the complainant. The Respondent is not a SAMED member therefore SAMED has no jurisdiction over the Respondent.	The complainant was advised to report the matter to Minister of Health and/or the South African Police Service.  Complainant indicated they would not be supplying the Respondent products going forward and would report them to the relevant authority should they become aware that the Respondent continues this activity.
5	The complaint was regarding an adverse event following a procedure done at a hospital. A member of SAMED was not mentioned in the complaint. No mention of the hospital or the doctor involved was made in the complaint.	The complainant was requested to report the matter to the relevant authorities; hospital management and the HPCSA.
6	The complaint was regarding the reuse of single-use devices.	The matter was referred to the relevant authority i.e. the South African Health Products Regulatory Authority (SAHPRA).

<b>7</b>	The complaint was regarding a company trading without a medical device establishment licence.	The matter was referred to the relevant authority i.e. the - South African Health Products Regulatory Authority (SAHPRA).
<b>8</b>	The complaint was regarding a company trading without a medical device establishment licence and thus of a regulatory nature.	The matter was referred to the relevant authority i.e. the South African Health Products Regulatory Authority (SAHPRA).
<b>9</b>	The complaint is regarding bribery and corruption allegations of providing “kickbacks” to surgeons for the use of their products through a third-party.	Investigation on-going.
<b>10</b>	The complaint is regarding comparative advertising.	Investigation on-going. Ethics Panel convened for a hearing.
<b>11</b>	The complaint is regarding provision of a recreational lunch for healthcare professionals.	The respondent provided a detailed response to the complaint and documentation as proof of legitimacy of the exchange of scientific and academic information at a venue they deemed fit for purpose.  The Independent Chair was satisfied and closed the complaint.
<b>12</b>	The complaint is regarding the untrained use of and incorrect reporting on a competitor device.	The respondent provided a response as to the opinion he provided the HCP upon the HCPs requests with the limitations on the information the respondent had access to. No evidence could be provided to indicate that the respondent has given an opinion on the efficacy of the complainant’s device.  The Independent Chair was satisfied and closed the complaint.
<b>13</b>	The complaint is regarding unpaid company taxes and the general unethical and irregular practices within the company.	The company is not a SAMED member. The complainant also referred the matter to the HAWKS, SAPS, the Commercial Crime Unit and the HPCSA. As this fall within their jurisdiction, the SAMED investigation was closed.
<b>14</b>	A company used the hotline to vet a SAMED member company.	The query was answered, and the matter was closed.

\* Whistleblowing is recognised as the most effective measure to guard against fraudulent or unethical activity within organisations. [The Medical Device Code of Ethical Marketing and Business Practice](#) (the Code) hotline is an anonymous tip-off mechanism available to any member of the public wishing to report contraventions of the Code. The hotline is independently managed and available 24/7.