

Statement on the MCA position with respect to the alignment of the MCA Code international codes.

(Decision taken by the MCA Board at a properly constituted meeting on 6th May 2019)

The MCA Code was tabled at MCA Board meeting of 6 May 2019, following a seven-month period of consultation with associations and members, directed by the MCA office and the CTAC committee. The Board accepted all changes universally supported at CTAC level and those proposed by the MCA legal adviser to ensure that the Code aligns with the amendments proposed to the Constitution. On the other hand, the amendments proposed to align the MCA code with the IFPMA code were not universally supported and were not accepted at the meeting. This decision was informed by the discussion points below:

- The major differences in approach between the IFPMA code and the MCA code would lead to unintended consequences for manufacturers of complimentary medicines and Medical Devices as,
 - o the IFPMA code does not apply to Medical Devices, and
 - o the IFPMA code does not apply to complimentary medicines;
- the South African code environment is unique in that it applies to a broad cross-section of industry rather than to mainly “research-based” companies and the approach it takes must respect this vision of a broad membership base;
- given that code compliance is still on a voluntary basis in this country, the objective of the code is to give a sound basis and guidance for application in the absence of any formal regulation. It should therefore not be a deterrent factor to other companies currently not aligning to any other formal regulation or code.
- the general industry practice, and indeed the MCA Code policy, is that within any one organisation, where more than one code has jurisdiction, the strictest code applies. Members are therefore not prohibited from applying the stricter standards of the IFPMA or other codes;
- at an appropriate time, if a decision is made to seek global code alignments, a deliberate policy decision needs to be made as to which code would be an appropriate benchmark.

The MCA has accessed many of the Codes from relevant jurisdictions and these will be made available on our website. However, until such time as a formal decision is made by the MCA to align with a global code, the standards of the MCA Code represent the minimum compliance standards for members of the MCA.

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