



CONSTITUTION

10 SEPTEMBER 2015

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Signatories to the Code of Marketing Practice on behalf of the first Members
of the Marketing Code Authority _____ 22/23

CONSTITUTION OF THE MARKETING CODE AUTHORITY

1. DEFINITIONS

- 1.1 “**Board**” means the Board of the Marketing Code Authority constituted through this Constitution;
- 1.2 “**Code**” means the Code of Marketing Practice as agreed to by all the trade associations listed in the Code and whose members become the members of the MCA, whether published in, acknowledged in or as part of the legal framework regulating health products;
- 1.3 “**Committee**” means any Committee constituted in terms of this Constitution and includes Adjudication Committees and Appeal Committees called upon to hear and rule on Code matters from time to time;
- 1.4 “**Conflict of interest**” or “**conflicted**” means that a person, company or any person representing a company has, direct business dealings with any party to a dispute or deliberation; or holds a specific position in relation to any subject-matter before any of the structures of the MCA; or where the person, company or person representing a company is involved in the same class of molecule or, in the same type of device or IVD device or business, and where s/he or it could potentially benefit from a ruling in a specific manner or direction;
- 1.5 “**Constitution**” means the Constitution of the Marketing Code Authority;
- 1.6 “**Industry sub-sector**” means a sub-sector of health products which are distinct, and subject to regulatory provisions that are different from those set for other sub-sectors and include, but is not limited to the medicines sub-sector, the OTC medicine sub-sector, the medical device sub-sector, the IVD sub-sector, the animal health sub-sector and any other subsector whose members may join the MCA from time to time;
- 1.7 “**Member/s**” mean the individual companies who belong to the trade associations that have signed up to the Code, and include any company not belonging to a trade association and who signs up and qualifies for membership in terms of this Constitution;
- 1.8 “**Panel**” means the panels constituted in terms of this Constitution and from which the members of Adjudication and Appeals Committees are, from time to time, appointed;

2. OBJECTIVES OF THE MCA

- 2.1 The Marketing Code Authority (the “**MCA**”) is a juristic body which is a voluntary association established to create a mechanism for the self-regulation of companies within industries bound by the Code of Marketing Practice (the “**Code**”) and which may be recognised by law as such.
- 2.2 The MCA is the body through which the enforcement of the Code takes place, in line with the principles embodied in this Constitution and the Code.

- 2.3 In order to fulfil its objectives, the MCA has to:
- 2.3.1 Ensure and maintain the ethical promotion and advertising of products within the scope of the Code by companies subject to the Act and the Code;
 - 2.3.2 Ensure that those bound by the Code maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements;
 - 2.3.3 Adjudicate on complaints and disputes in terms of the Code.
 - 2.3.4 Update and publish, on a regular basis, a code of practice for the marketing of health products
- 2.4 It is recognised that, in terms of Section 18C of the Medicines Act, all companies shall be bound by the provisions of this Code once incorporated into, or recognised by legislative provisions. Provision is therefore made in this Constitution for companies that do not belong to any trade association to subscribe to the Code and become members of the MCA until such time as the law requires of all companies to be bound by the Code and its enforcement mechanisms.

3 **MEMBERSHIP**

- 3.1 The first members of the MCA are the member companies of the trade associations listed in the Annexure(s) to the Constitution and Code.
- 3.2 The membership of the MCA shall consist of:
- 3.2.1 the first members of the MCA; and
 - 3.2.2 companies carrying on business in the Republic of South Africa as manufacturers, importers, distributors or agents of the products governed by the Code and who are not members of trade associations, which entities have agreed to be bound by the Code or who is by law bound by the Code, subject to the provisions of this Constitution.
- 3.3 Admission of all new members will be subject to the approval of the Board in its absolute discretion. Their eligibility will be assessed, *inter alia*, on the willingness to subscribe to the objects and functions of the MCA, as set out in this Constitution and the rules and policies as set, from time to time, by the Board.
- 3.4 Members may join at any time during a calendar year, and such member will be liable to pay the full membership fee and any other fees or levies payable. This fee will be pro-rated quarterly. Membership fees may be paid through the offices of the trade association(s) representing members to the MCA, and MCA membership fees may form part of the trade association membership fees.
- 3.5 Members may terminate their membership with the MCA by providing written notice thereof by no later than the 30th September of any calendar year. Failing to give the required written notice will render the member liable for the full annual MCA membership in respect of the following calendar year.
- 3.6 Non-members of the MCA may elect to participate in - and/or be subjected to the adjudication processes established by the Code, subject to the relevant provisions in the legislation in place governing the registration and marketing of health products. If based on

voluntary, case-by-case utilisation, each non-member has to agree to be bound by the decision of the MCA, as a pre-condition to the MCA admitting such a case by the respective non-members.

- 3.7 The MCA may formulate rules for the eligibility and admission of members, from time to time, subject always to the Act and the provisions of this Constitution.
- 3.8 Application shall be made on the official application for membership form of the MCA in use from time to time and such application shall be submitted to the Board via the Office of the Executive Officer (EO). Without in any way limiting the power of the Board, such form shall contain an undertaking by the applicant that upon admission to membership, it shall:
- 3.8.1 be bound by and accept the provisions of these Articles and any rules framed there under or policies laid down by the MCA, including but not limited to the Code and its adjudication processes; and
 - 3.8.2 treat as confidential any documents so marked by the MCA.
- 3.9 Every company admitted to membership of the MCA, shall nominate to the Executive Officer in writing from time to time a person who is a partner, member, director, owner or employee, as the case may be, of such entity as its representative together with an alternate who may act for him/her in his absence, and such person shall be permitted to attend meetings of members of the MCA, and to vote at such meetings on behalf of the entity that so nominated that person.
- 3.10 In the event that the company representative or the alternate nominated in terms of this clause is unable to attend a meeting of the members of the MCA, and unable to vote at such meetings in accordance with the procedures allowed in this Constitution, the company representative may nominate a representative from the relevant trade association to which that company belongs, and direct such trade association representative to attend such meeting and vote by proxy on the company's behalf.
- 3.11 A proposed member shall not be deemed admitted to membership until the annual membership fees and any other fees or levies payable at that point in time, have been paid to the MCA in full.
- 3.12 Every new member shall lodge with the Executive Officer the postal address, street address, fax number, telephone number and e-mail address to which communications may be directed by the MCA's office. The member is obliged to advise the MCA of any changes to the a foregoing.

4 APPLICATION FOR MEMBERSHIP

- 4.1 The MCA may formulate rules for the eligibility and admission of members, from time to time, subject to the provisions of this Constitution.
- 4.2 Application shall be made on the official application for membership form of the MCA in use, from time to time, and submitted to the Board via the office of the Executive Officer. Without in anyway limiting the power of the Board, such form shall contain an undertaking by the applicant that upon admission to membership, it shall:

- 4.2.1 be bound by and accept the provisions of this Constitution and any rules framed there under or policies laid down by the MCA, including but not limited to the Code and its adjudication processes; and
 - 4.2.2 treat as confidential any documents so marked by the MCA.
- 4.3 Trade associations may be required to assist in the processes of membership of the MCA by ensuring that MCA membership application forms of its members are completed and submitted to the office of the Executive Officer of the MCA, within time-frames set by the Board.
- 4.4 Every entity admitted to membership of the MCA shall nominate to the Executive Officer in writing, from time to time, a person who is a partner, member, director, owner or employee, as the case may be, of such entity as its representative together with an alternate who may act for him/her in his absence, and such person shall be permitted to attend meetings of members of the MCA, and to vote thereat on behalf of the entity that so nominated that person and all MCA notices will be issued to such a person.
- 4.5 A proposed member shall not be deemed admitted to membership until the annual membership fees and any other fees or levies payable at that point in time, have been paid to the MCA in full.
- 4.6 Every new member shall lodge with the Executive officer, the name of its representative, the postal address, street address, fax number, telephone number and e-mail address to which communications may be directed by the MCA's office. The member is obliged to advise the MCA of any changes to the a foregoing.

5 POWERS OF THE MARKETING CODE AUTHORITY

The MCA shall have all the powers necessary to achieve its objectives including, without limitation, the powers:

- 5.1 to appoint a Board, in the manner provided in its Constitution, in which shall vest the authority and responsibility to achieve the objectives and exercise the powers of the MCA;
- 5.2 to appoint and remunerate an Executive Officer to fulfil such administrative functions as are provided for in the Code and this Constitution, and as may be determined by the Board from time to time;
- 5.3 to contract any of its functions, including the right to administer the Code and its enforcement, to any entity it finds competent and suitable to fulfil such functions, subject to the oversight of the Board and in terms of an agreement setting out the scope, nature and duration of such functions;
- 5.4 to enter into co-operation and other agreements with any other trade association, with any group and/or institution/organisation, in order to further the objectives of the Code and health sector-wide adherence to the Code of Marketing Practice;

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- 5.5 to ensure that all trade associations and, in particular, trade association heads, are kept abreast of all developments in relation to the Code, whether training, reviews, guidance's issued and/or enforcement;
- 5.6 to ensure that all external, but affected stakeholders, such as healthcare professionals, software houses, marketers, and others are informed on the Code and developments relating to Code matters;
- 5.7 to appoint and remunerate such other employees as may be required, from time to time;
- 5.8 to constitute and appoint Adjudicating Panels and - Committees and Appeal Panels and - Committees in terms of the provisions of this Constitution and to fulfil the functions outlined in the Enforcement Section of the Code;
- 5.9 to appoint persons to the Legal Panel;
- 5.10 to ensure compliance with the provisions of the Code and to make or recommend amendments to the Code from time to time and within any applicable legal frameworks;
- 5.11 to impose sanctions (including but not limited to penalties which may be of a financial nature) for any breach or contravention of this Code by a Company or for any failure to fulfil- or adhere to any undertaking and/or ruling;
- 5.12 to print, publish and circulate whether electronically or otherwise, or to assist and subsidise, at its discretion, the printing, publishing and circulation of an official publication and newspapers and periodicals devoted to the healthcare industry;
- 5.13 to develop, refine and publish a set of Code Guidelines and ensure that they remain relevant and up to date.
- 5.14 to provide guidance, training and assessment of competence on the Code, which guidance, training and assessment will, however, not bind the MCA in any manner to adjudicate or rule in any matter in any particular fashion;
- 5.15 to monitor advertise and/or promote health products, in whatever form, including but not limited to journal advertising, internet advertising and electronic advertising by Companies and practices relating to the interaction between companies and healthcare professionals as defined in the Code;
- 5.16 to request a Company to submit copies of any advertising and/or promotional material, including copies of the certificates authorising such material as well as copies of briefing instructions furnished to Healthcare Sales Representatives of such Companies;
- 5.17 to indemnify the Executive Officer, any office-bearers, members of Boards, Committees and Panels against all losses, costs and damages which they or any of them may be put to in the *bona fide* exercise and discharge by them of the powers and duties conferred and imposed upon them and to provide for the MCA and any such persons to be insured against any legal claim relating to their work for the MCA;

- 5.18 to open banking accounts in the name of the MCA, to draw, accept and endorse cheques, bills of exchange and promissory notes in connection with the business of the MCA;
- 5.19 to purchase, hire or otherwise acquire such land, houses, buildings, furniture, fixtures and fittings, equipment or any other property, and to improve, lease, sell or otherwise deal with them;
- 5.20 to invest any moneys of the MCA on deposit in a bank or building society, or in a savings account in a bank or building society, or on first mortgage on immovable property, provided the amount lent on mortgage shall be limited to two-thirds of the sworn valuation of the property, with power, from time to time, to vary any of the investments and re-invest the proceeds of any sale thereof in the manner aforesaid;
- 5.21 generally, without limitation, to do anything it may consider necessary or proper for the attainment of its objectives;
- 5.22 remunerate employees, consultants, advisors, investigators and the like.
- 5.23 co-opt members or persons as appropriate
- 5.24 In the event of a disagreement on matter relating to Code and guideline revisions, all members should cast this voting via their respective trade associations where applicable. The respective MCA board member will take their majority vote for the MCA make a decision.

6 **BOARD MEMBERS: COMPOSITION**

- 6.1 The determination of the general policy and direction and control of the operations of the MCA and its affairs, in line with the objects of this Constitution and bearing in mind the substantive and procedural provisions of the Code, shall be vested in the Board.
- 6.2 The Board will consist of up to 13 members, comprised as follows:
 - 6.2.1 **Members with voting power:**
 - 6.2.1.1 A nominated representative of each of the trade associations listed below, unless any trade association declines to take up its seat on the Board and in which case such decline will not lead to a vacancy on the Board and one Board seat will be reserved for non-aligned members of the MCA:
 - 6.2.1.1.1 Innovative Pharmaceutical Association of South Africa (IPASA)
 - 6.2.1.1.2 The Self-Medication Manufacturers' Association of South Africa (SMASA);
 - 6.2.1.1.3 Pharmaceuticals made in South Africa (PHARMISA);
 - 6.2.1.1.4 The South African Animal Health Association (SAAHA);
 - 6.2.1.1.5 The South African Medical Device Industry Association (SAMED);
 - 6.2.1.1.6 The Southern African Laboratory Diagnostics Association (SALDA);
 - 6.2.1.1.7 A Representative of non-aligned MCA members (INDEP).

6.2.2 Members without voting power:

6.2.2.1 One person nominated by a consumer group which, in the opinion of the Board, represents the interest of healthcare consumers;

6.2.2.2 A member from the Legal Panel ex officio;

6.2.2.3 The Executive Officer ex officio.

- 6.3 Should further associations be established, which in the opinion of the then representatives of the MCA should become part of MCA Board, such associations will become eligible to nominate a representative as a member of the Board as provided for in this Clause and all other Clauses relating to the Board will be interpreted accordingly.
- 6.4 The Executive Officer of the MCA will act as the Secretary of the Board.
- 6.5 One member of the Board will be nominated at an AGM by- and from amongst members of the MCA who do not belong to any trade association.
- 6.6 The Board may, in its sole discretion, co-opt non-voting board members to inform its work.
- 6.7 Each of the trade associations shall have the power to appoint any person to act as an alternate Board member in the place of its appointed member and at its sole discretion terminates such appointment.
- 6.8 Each alternate Board member shall (except as to the power to appoint an alternate) be subject in all respects to the terms and conditions existing with reference to the other members of the Board. Each alternate Board member, while so acting, shall exercise the same powers and discharge all the duties of the Board member s/he represents. An alternate Board member shall be entitled to receive notices of meetings of the Board and to attend and vote but only at any such meeting at which the Board member in whose stead s/he acts is not personally present. The alternate Board member counts towards a quorum at any such meeting.
- 6.9 After the first three years of operation of the MCA, and in alphabetical order of the names of the trade associations at the time, the first three (3) trade associations shall nominate a representative to the board to serve for a one-year term, the second three (3) trade associations shall nominate a representative to the board to serve for a two-year term, the remaining trade association(s), non-aligned members or consumer groups shall nominate a representative to the board to serve for a three-year term. Thereafter, all board members nominated to replace the outgoing board members shall serve for a term of three (3) years, or until their successors have been elected.
- 6.10 The Board may designate from amongst its members a person or persons to represent the MCA at all public functions, failing which the Chairperson, or in his/her absence or unavailability, the Vice-Chairperson fulfils this function.
- 6.11 The Board may designate from amongst its members a person to make any public announcement or public response on behalf of the MCA, failing which the Chairperson, or in his/her absence or unavailability the Vice-Chairperson fulfils this function, which responsibility may be delegated to the Executive Officer.

6.12 In order to prevent conflicts of interest, a member of the Board may not act in a professional capacity for the MCA and his/her company shall be not be entitled to any remuneration for any professional services rendered as part of his or her tenure as member of the Board and any member of the Board which has a conflict of interest in any matter before the Board, has to recuse him/herself from any such deliberation and decisions.

6.13 No person who is an employee of a member of the MCA and who serves on a Panel, Committee or any other structure of the MCA, whether a standing or *ad hoc* structure, may charge any fees for services rendered to the MCA, but the Board may, in its sole discretion, determine reasonable honoraria payable to any person, should the financial situation of the MCA so allow.

7 TERMINATION OF MEMBERSHIP OF THE BOARD

A member of the Board shall vacate his or her office if:

7.1 S/he resigns his office by notice in writing to the Chairperson and such resignation will be effective from the date at which such resignation occurs; or

7.2 S/he is, without prior consent from the chairperson, absent from 2 (two) consecutive meetings of the Board; or

7.3 His/her nominating trade association or group cease to be a representative trade association of the MCA and/or his/her company cease to be a member of the MCA; or

7.4 A unanimous resolution is passed by all other members of the Board present at a meeting declaring that:

7.5 a member of the specific Board has placed the MCA into disrepute, and/or that it is undesirable in the interest of the MCA that s/he shall remain a member of the Board; and/or

7.6 s/he has acted in any improper manner; and/or

7.7 s/he is not a fit and proper person to hold the position of a member of the Board, which might include cases where the company that the Board member is an employee of, has committed a serious and/or repeat breaches of the Code and/or has failed to implement findings of the MCA relating to such serious and/or repeat breaches.

7.8 provided that no such resolution shall remain effective unless the notice convening the meeting has indicated that the meeting would consider such resolution and the said member has had the opportunity of attending in order to state his or her case and to answer any charge or charges made against him or her.

8 BOARD: MEETINGS AND PROCEEDINGS

- 8.1 The members of the Board shall annually, after the AGM, elect one of the Board members to be the chairperson of the Board and shall also elect a vice-chairperson after a process of nominations made and accepted in writing to the office of the Executive Officer at least 48 (forty-eight) hours prior to the first post-AGM meeting of the Board. A vacancy of the Chairperson prior to the termination of his/her elected period in office for whatsoever cause, shall be filled by the vice-chairperson until the next meeting of the Board where a new chairperson shall be elected by the Board.
- 8.2 A quorum for meetings of the Board shall be five Board members (excluding the Executive Officer), provided that in the event of further associations becoming eligible to nominate members, the number needed for a quorum shall be increased by one for each new joining association. Equally in the case of an association terminating its membership of the MCA, the quorum shall be decreased by one for each association terminating its membership with the MCA
- 8.3 The Board shall meet for the regular despatch of business, adjourn or otherwise regulate its meetings as it deems fit. The Board may act notwithstanding any vacancy providing the number of Board members does not fall below the number required for a quorum.
- 8.4 The Board shall in all instances aim to reach consensus on all matters before it, failing which a majority of members present will decide any such matter and in the case of an equality of votes, the chairperson of the Board shall have a casting vote.
- 8.5 Where a matter pertains to an issue found in a section of the Code that only pertains to one specific industry-sector, such industry sector representatives on the Board shall have a veto in all such matters. In the case of a dispute as to whether such matter is a common matter, or an industry-specific matter, an independent arbitrator will be appointed by the Board to resolve whether the matter is an industry-matter or a common matter.
- 8.6 Any resolution in writing signed by a majority of the Board members shall be as valid and effectual as if it had been passed at a meeting of the Board.

9 POWERS OF THE BOARD

- 9.1 The Board shall:
- 9.2 exercise all the powers provided for in this Constitution, save for the powers awarded to the Annual General Meeting, on behalf of the MCA;
- 9.3 manage and conduct all the affairs of the MCA, including but not limited to the adoption of Policies and Procedures relating to Good Corporate Governance of the MCA and all its structures;
- 9.4 administer and conduct all the financial affairs of the MCA, ensure that all required systems and principles for good corporate governance are in place and cause minute-books, proper records and documents to be kept;

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- 9.5 determine, from time to time, the forms and fees in respect of complaints and appeals and the conditions for the waiver of such fees;
- 9.6 determine, from time to time, the list and quantum of sanctions, penalties, costs and fines, as well as institutions or authorities for referrals of matters adjudicated upon by any of the MCA Committee;
- 9.7 determine, from time to time, the levies and charges in respect of other services, such as training, assessment and general guidance, which may be provided by the MCA to Companies, Associations, Members and other stakeholders;
- 9.8 determine, from time to time, the membership forms, fees and levies of the MCA;
- 9.9 review the principles embodied in the Code and review the enforcement and governance provisions and make- or cause amendments to be made or make recommendations to any appropriate regulatory authority on amendments proposed by it or any such authority if required;
- 9.10 approve and amend Guidelines to the Code as practical manifestations of the implementation or application of the Code and which would be used by Adjudication and Appeal Committees to guide the consideration of matters before it, in which the interpretative approach as set out in the interpretation clause of the Code shall be followed;
- 9.11 compile and publish annual reports on complaints received by the MCA in a format as approved by the Board and according to Board policy set in terms of this Constitution and submit these reports to the Department of Health and/or any relevant authority;
- 9.12 have the power to delegate any of its powers or functions to any committee(s) or person(s) (with or without the power of sub-delegation and/or with or without conditions as it may in its discretion deem fit) and shall have the power to vary or withdraw or increase or decrease the powers or functions delegated at any time;
- 9.13 publish or cause to be published regular reports to the members setting out details of the tasks which had been undertaken by the Board, the Adjudicating Committee and Appeal Committee in the preceding year;
- 9.14 ensure the publication of the outcomes of hearings from time to time in line with policy set by the Board; and
- 9.15 put in place every reasonable effort to expand the membership of the MCA and the acceptance of the Code to non-trade association companies.
- 9.16 in the event of disputes that involve a whole sector/sectors or constituency/constituencies of the MCA, the Board –
- 9.17 shall appoint an independent and experienced mediator in order to mediate the dispute.

9.18 shall, should the dispute not be resolved, call a Special General Meeting to put the matter to a vote to the general membership of the MCA.

10 **EXECUTIVE OFFICER**

10.1 The Board shall delegate to the Executive Officer by resolution all such powers as are necessary to enable the Executive Officer to conduct and perform the functions and duties which are provided for in this Constitution and in the Code.

10.2 Notwithstanding anything to the contrary contained in this Code, the Executive Officer shall not, attend any hearing, be it conducted in person, attend or be part of any hearings before an Adjudicating Committee or Appeal Committee, or be part of any discussion, consideration or deliberation relating to the case irrespective of whether the matter is dealt with in person or on paper.

10.3 The Executive Officer shall ensure that complete records are kept of all MCA matters, including complete histories of complaints, investigations, hearings and any other Code matter, in a manner and format and for a duration as is determined by Board policy from time to time.

11 **COMMITTEES, SUBCOMMITTEES AND PANELS**

11.1 The Board may appoint committees, subcommittees and panels for such objects and purposes and with such powers and such duties as may be decided upon consistent with carrying out the object and interest for which the MCA had been formed and in line with the specific procedures and criteria set by the Code(s) administered by the MCA. The Board shall at least appoint the following structures, which shall be entrusted with interpreting, applying and enforcing the provisions of the Code:

- 11.1.1 An Adjudicating Panel, from which members of an adjudication committee will be appointed from time to time;
- 11.1.2 An Appeal Panel, from which members of Appeals Committee will be appointed from time to time;
- 11.1.3 A Legal Panel, from which appropriate legal experts will be drawn for the Committees of the MCA.

11.2 The Board may appoint a Code Technical Advisory Committee to provide it with technical advice and the Board may delegate to it any matter to investigate and to report back to the Board on.

11.3 The Executive Officer shall at such times as s/he may consider appropriate approach the Associations and non-aligned members to call for nominations of persons considered by the Associations to be eligible to be included as members of the Adjudicating-, Appeal and Legal Panels, which nominations have to be accompanied by a curriculum vitae of each nominee and declarations relating to possible conflicts of interest.

11.4 The Executive Officer shall appoint for the purpose of guidance or the enforcement of the Code as the case may be, the following Committees from the above panels, and in line with provisions of this Constitution and the Code, ensuring a good representation of persons

from the various sectors to which the Code applies to ensure that ex-parte , adjudication and appeal committee members in any particular case have an understanding of the specific sector to which a matter or complaint applies:

- 11.4.1 An Ex-Parte Committee, which will consider a matter made on an ex-parte basis in relation to the interpretation or application of the Code, and make a ruling for purposes of clarification on the matter provided that such ruling shall be for guidance purposes only and considered non-binding on any formal complaint lodged with the MCA;
- 11.4.2 An Adjudicating Committee, which will hear any complaint before it, make a finding in relation to the complaint and, if applicable impose an appropriate sanction;
- 11.4.3 An Appeals Committee, which will hear an appeal from any party aggrieved by the outcome of the process by the Adjudication Committee, make a finding in relation to the appeal and, if applicable, vary or confirm a sanction imposed by the Adjudication Committee or impose a new sanction.

11.5 The Executive Officer shall, in his or her sole discretion decide upon the names of the persons which s/he deems appropriate to appoint as members of the Adjudicating Panel, as members of the Appeal Panel and as members of the Legal Panel and the Executive Officer may remove from any panel, after following a fair process and providing the person with an opportunity to state his/her case, a member of such Panel who has brought the MCA in disrepute, and/or who has breached any of the provisions of this Constitution and/or the enforcement process(es) stipulated in the Code of Marketing Practice.

11.6 The Adjudicating Panel and Appeal Panel will each consist of a minimum of 12 (twelve) individuals who shall include persons with medical, regulatory and marketing expertise, skills and qualifications, who shall be eligible to serve for a maximum period of 5 (five) years.

11.7 The Legal Panel will consist of attorneys and/or advocates and/or judges of at least 5 (five) years standing in South Africa and with substantial experience in the health products market and/or health products industry matters, the appointment of which will be indefinite or until such person resigns from the Legal Panel.

11.8 When a person has been appointed to the Adjudicating or Appeal Panels and the period of the appointment (or re-appointment) is completed or due to be completed, such person may, in the sole discretion of the Board, be re-appointed to the Adjudicating or Appeal Panels for such period as it may determine.

11.9 A person may not simultaneously serve as a member on the Adjudicating and Appeal Panels.

11.10 All persons appointed to any of the panels, will sign an agreement in terms of which they agree:

- 11.10.1 that when they sit as members of any Committee, to keep all processes, deliberations and rulings of such Committee confidential;
- 11.10.2 that when they are nominated to sit as a member of any Committee, to immediately indicate any conflict of interest they may have in the matter to be considered by such Committee which may cause a conflict of interest and to

recuse themselves from such sitting and/or all deliberations.

11.11 The Executive Officer shall not attend or be part of any hearings before an Adjudicating Committee or Appeal Committee, if such hearings are in person, and/or not be involved in any discussions, considerations and/or deliberations should hearings be conducted on paper or in person.

11.12 All Committees will exercise their duties in accordance with the processes and principles set out in the Code.

11.12.1 The Executive Officer shall after receiving an ex-parte request, and disposing of all criteria and processes set by the Code, appoint from amongst the members of the Adjudicating or Appeal Panel, an Ex-Parte Committee consisting of at least three persons (or any odd number of persons) and shall document the substantiation for the selection, provided that at least 50% or more of the committee members thus appointed are au fait with the specific industry to which the specific ex parte request relates.

11.12.2 The Executive Officer shall (may), after receiving a complaint or appeal, and disposing of all criteria and processes set by the Code, appoint one person from the Legal Panel and at least two persons (or any even number of persons) from amongst the members of the Adjudicating or Appeal Panel, to an Adjudicating or Appeal Committee as the case may be, and shall document the substantiation for the selection, provided that at least 50% or more of the panel members thus appointed are au fait with the specific industry to which the specific complaint or appeal relates.

11.13 No person shall be appointed to a Committee if s/he is in any way conflicted.

11.14 Pending the hearing, the Executive Officer shall make known to the parties the identity of the individuals appointed to the Committee, for the sole purpose of providing opportunity to any party to raise potential conflicts of interest. Parties shall refrain from using this knowledge for any commercial or other advantage, and shall ensure that this information do not become public, and shall also refrain from victimising or placing any influence or pressure on such appointed individuals.

11.15 The quorum for an Adjudicating or Appeal Committee shall be three, one of which shall be appointed as Chairperson by the Committee.

11.16 The Adjudicating or Appeal Committee shall have the power, in its sole discretion, to co-opt at the commencement of any hearing or at any other time, any person or persons where it considers that such person or persons will be able to assist in the hearing and deliberations. The co-opted person(s) will not have a vote.

11.17 Any member who has absented himself from any part of the hearing shall not take any further part in those proceedings. The absence of a member of an Adjudicating or Appeal Committee on any occasion during the hearing shall not affect the validity of such proceedings, provided the number of remaining members meets the quorum requirement.

11.18 The Adjudicating Committee and Appeal Committee shall have the powers awarded to it by the Code and fulfil its functions in terms of the provisions of the Code, which includes those relating to special considerations and penalties as set out in the Code.

11.19 If deemed expedient by the Board persons whose companies are not members of the MCA may be appointed to the Adjudication or Appeal Panel or to any MCA committee save that no person who is not a partner, director, manager or other permanent official of a member shall be eligible for membership of any committee to which matter affecting the constitution or financial interest of the MCA are referred, and no member may have representation on a committees, boards or panels considering a matter in which it is involved and avoid instances of conflict of interest..

11.20 The operation of all committees, panels or boards shall be in accordance with rules as determined, from time to time, by the Board and, if applicable, within the scope set by the Code applicable to such committee, panel or board.

11.21 The Executive Officer shall ensure that mechanisms and systems are in place to ensure that all documentation and information relating to the Code, its Guidelines and all communications, enforcement processes, rulings, decisions, deliberations and all related information are kept in a secure manner for such periods as the Board may, from time to time determine, or as determined by law.

12 GENERAL MEETINGS

12.1 The MCA shall hold its first annual general meeting within twelve months after the date of signature of this Constitution by the trade associations representing the members of the MCA and shall thereafter once in every financial year hold an annual general meeting at such time and place that may be determined by the Board provided that not more than fifteen months shall lapse between any two such general meetings.

12.2 Other general meetings may be held at any time, when called by the Board or in writing by at least 10% of its members or three of the trade associations representing members of the MCA.

12.3 Annual general meetings and other general meetings shall be held at such time and place as the Board shall determine.

13 NOTICE OF GENERAL MEETINGS

13.1 An annual general meeting and a meeting called for the passing of a special resolution shall be called by not less than 21 (twenty one) calendar days' notice in writing and any other general meeting shall be called on not less than 14 (fourteen) calendar days' notice in writing. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and shall specify the place, the day and the hour of the meeting and the general nature of the business and shall be given to all members of the MCA, either through their representative trade associations or directly at the addresses provided to the Executive Officer upon joining the MCA, provided that a meeting of the MCA shall, notwithstanding the fact that it is called by shorter notice than that specified in

this clause, be deemed to have been duly called if it is agreed by a majority in numbers of the members.

13.2 The accidental omission to give notice of a meeting to, or the non-receipt of notice of a meeting by, any member shall not invalidate the proceedings at such meetings.

14 **QUORUM AND PROCEEDINGS AT GENERAL MEETINGS**

14.1 The business of the annual general meeting of members shall be:

14.2 to receive and consider the annual report of the Board, which should include a report on all the matters that were adjudicated in terms of the Code, all training and education undertaken under the auspices of the Board and any matter within the objectives of the MCA;

14.3 to receive and consider the audited income and expenditure accounts and balance sheet with the auditor's report thereon;

14.4 to elect an auditor or auditors whose remuneration will be fixed by the Board;

14.5 to confirm the nominations of the Board as provided for in this Constitution;

14.6 to confirm the membership fees and/or to establish the membership fees and/or levies for the current financial year;

14.7 to transact any business brought under consideration by the reports of the Board and the Executive Officer of the MCA; and

14.8 to transact any other business as may under this Constitution be transacted at a general meeting, including but not limited to the business objects outlined in this Constitution.

14.9 All other business laid before any other general meeting shall be considered special business.

14.10 No business shall be conducted at any general meeting unless a quorum of members is present at the time when the meeting proceeds to business. A member of the MCA shall be regarded as present when represented by a representative duly appointed or nominated in terms of clause 3.9.2 herein by the member, or by such member providing his/her vote(s) to the Executive Officer on the form designed for that purpose prior to the meeting. Save as in herein otherwise provided, two-fifths of the members entitled to be present and to vote at such meetings shall be a quorum, provided that there will always be at least 11 (eleven) members present in person which votes shall be either by email on the designated voting form or by proxy provided to another member or duly nominated representative present at the meeting.

14.11 If, within ten minutes after the time appointed for a meeting a quorum is not present, the meeting if convened upon a request of members shall be dissolved; in any other case it shall stand adjourned to the same day in the next week at the same time and place, or if such place is not available, to such other place as the Chairperson may appoint, or should

that day be a public holiday, then it shall be adjourned to the first business day following such public holiday at the same time, and if at such adjourned meeting a quorum is not present, those members who are present shall constitute a quorum and may transact the business for which the meeting was called.

14.12 The Chairperson of the Board shall preside at every general meeting, and in his/her absence the Vice Chairperson, and in the absence of both such office bearers or if neither of them be willing to act as Chairperson, the members of the Board present shall choose one of their number to act or if only one member of the Board be present, s/he shall preside as Chairperson if willing to act. If no member of the Board shall be present, or if all the members of the Board present decline to take the Chair, the members of the MCA present shall choose one of their number to act as Chairperson.

14.13 The Chairperson may with the consent of any meeting at which a quorum is present (and shall if so directed by the meeting) adjourn the meeting from time to time, and from place to place, but no business shall be transacted at any adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place. Save where the meeting is adjourned for thirty days or more, notice of the meeting need not be given to members.

14.14 The Executive Officer of the MCA and the Board shall act as the Secretary of the MCA at all its General Meetings.

14.15 Any minutes of resolutions and proceedings at general meetings made in one of the minute books of the MCA, if signed by a person purporting to be the chairperson of the meeting to which it relates, or by any person present thereat and duly appointed by the Board to sign the same in his/her place, or by the Chairperson of the next succeeding meeting, shall be receivable as the evidence of the facts stated therein. Minutes must be sent to all members within two weeks following the meeting

15 PROXIES AND VOTES OF MEMBERS AT GENERAL MEETING

15.1 At any general meeting a resolution put to the vote of the meeting shall be decided on a show of hands, unless a secret ballot is requested prior to the vote by either the Chairperson at his/her discretion or at least 5 (five) members present in person or by proxy.

15.2 After a vote, the chairperson of the meeting shall declare that a resolution has been either carried or not carried, or carried by a particular industry sub-sector as is prescribed in this Constitution for matters which are unique to a specific industry sub-sector.

15.3 In the case of an equality of votes, whether on a show of hands or on a poll, the chairperson of the meeting shall be entitled to a second or casting vote.

15.4 Where a matter is such that it is, on the agenda of the matters of a General Meeting circulated as a matter that affects a particular sub-sector of the industry only, after being determined as such by the Board in terms of the powers awarded to it in this Constitution, including the powers relating to the appointment of an arbitrator, only members belonging to sub-sector would be entitled to vote in such matter.

15.5 A form appointing a proxy may be in the form which the Board may approve, from time to time and, except for the provisions of clause 3.9.2 herein, no outside entity may act as proxy for a member, i.e. all proxies have to be carried by other entities who are members of the MCA.

15.6 Notwithstanding anything to the contrary contained herein, members may participate in and act at any general meeting through the use of a conference telephone or other communications equipment including without limitation by way of videoconference equipment. For the avoidance of doubt, a member's show of hands may be confirmed orally in the event a member participates by way of conference telephone or, in the case of a secret ballot, by means of persons designated by the Executive Officer at such places to count and verify votes thus cast.

16 **RESOLUTIONS**

16.1 Resolutions submitted by members for consideration at an annual general meeting of the MCA shall be placed on the agenda for a meeting provided that 14 (fourteen) calendar days' notice of such resolution has been given to the Secretary in writing. The Board shall at its discretion, have the right to submit resolutions for discussions at any annual general meeting. Such resolution shall not be subjected to the time limit aforementioned.

16.2 Matters appearing on the official notice or programme of business to be transacted at any general meeting shall be disposed of before any additional matter is discussed. Matters of urgency may, however, be discussed at any such meeting, when a majority of not less than 75% (seventy five percent) of the members present is in favour of such matter being discussed.

16.3 The resolutions and decisions which have been decided upon at any general meeting shall be put into effect by the Board, which shall report on the action taken at the next ensuing annual general meeting, unless determined otherwise in such a resolution or decision and subject to the provisions of this Constitution.

17 **RESERVE FUND**

The Board may establish or authorize the establishment of a reserve fund or funds for the purpose of meeting contingencies or for the furtherance of any objects of the MCA and such fund or funds may be invested as the Board directs.

18 **ACCOUNTS**

18.1 The financial year of the MCA shall be from the 1st of January to the 31st of December of the same year.

18.2 Proper books of accounts shall be kept to exhibit and explain the transactions and financial position of the MCA, and in particular proper books of account shall be kept with respect to:

18.3 all sums of money received and expenditure by the MCA and the matters in respect of which such receipt and expenditure takes place; and

18.4 the assets and liabilities of the MCA.

18.5 The books of account shall be kept at the office or at such other place as the Board thinks fit, and shall at all times be open to inspection by the members of the Board. No member (other than a member of the Board) shall have any right of inspecting any account or books or document of the MCA except as conferred by these Articles or authorized by the Board.

18.6 The Board shall at least once in every year lay before the MCA in Annual General Meeting a statement of income and expenditure, and a balance sheet in such a form and containing all such particulars as after required by these Articles, both made up to date not more than six months before the meeting. Copies of these documents shall be sent to every member with notice of the general meeting.

18.7 Every balance sheet shall be signed by the Chairperson of the Board and shall have attached to it a report by the Board in respect of the state of the MCA's affairs and the amount (if any) which the Board have carried or proposed to carry to reserve. It shall also have attached to it the auditor's report.

19 **AUDIT**

19.1 At least once in every year, the accounts of the MCA shall be examined and the correctness of the income and expenditure account and balance sheet ascertained by one or more auditor or auditors.

19.2 The auditors or auditors shall be appointed and their duties regulated in accordance with this Constitution.

20 **NOTICES**

20.1 A notice may be given to any member either by advertisement or personally, or by sending it through the post in a prepaid letter addressed to such member at the address supplied by it to the MCA for the giving of notices to it, or by fax transmission, to the number supplied by it, or by electronic mail to the address supplied by it for the giving of notices and addressed to the person indicated by the member as the correct addressee of such notifications. It would not constitute a breach of this Constitution if, for the sake of expediency and efficiency, notice to members who are members of trade associations, are provided to such members by / through a notice addressed to their trade association.

20.2 Any notice, if given by post, fax or email, shall be deemed to have been served at the time when the letter, fax or email has been sent and shall be sufficient to prove that the letter, fax or email containing the notice was properly addressed.

21 REPRESENTATION

The MCA may sue or be sued in any court of law, in its own name. All power of attorney, bonds, deeds, contract and other documents which may have to be executed shall be signed by any number of the members of the Board for the time being authorized so to do by a resolution of the Board as the delegate of the MCA.

22 BANKING ACCOUNT

A banking account shall be opened in the name of the MCA and all cheques drawn thereon shall be signed in such a manner as the Board may from time to time determine, provided that all cheques shall be signed by at least 2 (two) signatories, one of whom shall be a member of the Board, including potentially the Executive Officer.

23 SPECIAL CONDITIONS

To the extent that the MCA is approved by the Commissioner for SARS for the purposes of section 30B of the Income Tax Act:

- 23.1 The Board will consist of at least three persons, who are not connected persons in relation to each other, to accept the fiduciary responsibility of the MCA for income tax purposes
- 23.2 No single person will directly or indirectly control the decision-making powers relating to the MCA;
- 23.3 The MCA will not directly or indirectly distribute any of its funds or assets to any person other than in the course of furthering its objectives;
- 23.4 The MCA will utilise substantially the whole of its funds for the sole or principal object for which it has been established;
- 23.5 No member will directly or indirectly have any personal or private interest in the MCA;
- 23.6 Substantially the whole of the activities of the MCA must be directed to the furtherance of its sole or principal object and not for the specific benefit of an individual member or minority group;
- 23.7 The MCA will not have a share or other interest in any business, profession or occupation which is carried on by its members;
- 23.8 The MCA will not pay to any employee, office bearer, member or other person any remuneration, as defined in the Fourth Schedule to the Income Tax Act, which is excessive, having regard to what is generally considered reasonable in the sector and in relation to the service rendered;

SELF-MEDICATION MANUFACTURERS ASSOCIATION OF SA (SMASA)

On behalf of its members in terms of the provisions of its Constitution, that recognizes the Code and its mechanisms:

Signed: Authorised representative

Date

THE SOUTH AFRICAN ANIMAL HEALTH ASSOCIATION (SAAHA)

Only on behalf of its members subject to the Code due to the animal health products falling with the ambit of the Medicines Act:

Signed: Authorised representative

Date

THE SOUTH AFRICAN MEDICAL DEVICES INDUSTRY ASSOCIATION (SAMEDI)

On behalf of its members in terms of clause 3.3 of its Articles of Association:

Signed: Authorised representative

Date

SOUTHERN AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION (SALDA)

On behalf of its members in terms of clause 3.4 of its Constitution:

Signed: Authorised representative

Date

[Amendment as adopted at the Special General Meeting on 13th March 2013 in terms of clause 23 of this Constitution]

[Amendment as adopted at the 2nd Annual General Meeting on 13th September 2013;
Clauses amended: 1.4; 1.7; 5.11; 6.2.1; 9.9; 9.11; 10.2; 11.10.2; 11.11; 11.17
Clauses added: 5.23; 5.24; 9.10; 9.16; 9.17; 9.18; 14.10; 20.1]

[Amendment as adopted at the 3rd Annual General Meeting on 24th November 2014;
Clauses amended: 3.9.1; 6.2; 11.4; 11.4.2; 11.4.3; 11.13; 14.10; 15.5
Clauses added: 3.9.2; 6.4; 6.9; 11.4.1; 11.13.1;11.13.2]

[Amendment as adopted at the 4th Annual General Meeting on 10th September 2015;
Clauses amended: 3.4; 8.2 Clauses added: 3.5]