



Giving Life Back

MULTIPLE SCLEROSIS AUSTRALIA ('MSA')

POLICY AND PRACTICES IN RELATIONSHIPS WITH THE PHARMACEUTICAL AND MEDICALLY-RELATED PRODUCTS AND SERVICES INDUSTRIES

Note that references in this Policy to 'MSA' include the following entities: Multiple Sclerosis Australia, Multiple Sclerosis Research Australia ('MSRA') and their member organisations listed below in the States or Territories unless otherwise specifically excluded. References to the 'Company' refer to any pharmaceutical manufacturer, supplier or marketer, or other health related industry or supplier with whom MSA may have a relationship.

Members

The Multiple Sclerosis Society of Western Australia (Incorporated)

The Multiple Sclerosis Society of South Australia and Northern Territory Incorporated SA

The Multiple Sclerosis Society of Tasmania

Multiple Sclerosis Society of Queensland

Multiple Sclerosis Limited operating in ACT/NSW/VIC.

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1. Background

1.1 MSA has formed mutually beneficial relationships with the corporate sector over many years. The development of medicines specifically to modify the course of multiple sclerosis has led to growing interest in the work of MSA by Companies that may wish to support or develop a relationship with MSA. These include manufacturers and suppliers of medicines, medical devices and aids to daily living, dietary supplements, health management organisations, nursing/homecare agencies and insurers.

1.2 While MSA and Companies may share common values in regard to research, public health and philanthropy, the Companies usually have an expectation of commercial return, direct or indirect. MSA acts generally in the interests of people affected by multiple sclerosis. It is therefore essential for MSA to be clear about where those interests overlap and where they diverge. For example, while it is in the interests of people affected by multiple sclerosis that medicines, devices or services are made available according to need, increasing sales of the products or market share are purely a commercial objective.

1.3 Support from the Companies for the work of MSA is accepted in various forms. These include information about research programmes, data arising from research such as trials, information for both professional and lay audiences about products, support for educational programs, conferences, publications, donations, fundraising events, corporate advertising in an MSA publication and MS research projects. However, in accepting support from the Companies, MSA recognises that the support is generally desirable for it to be seen to be proportionate, independent and balanced or it may be perceived by people affected by multiple sclerosis or their professional and volunteer caregivers, or the concerned public, as promoting products or services. Equally, there could be a perception that funds provided to MSA for its programmes contribute to the price (cost) of the relevant product or availability. MSA will take all reasonable steps to ensure that there is no basis for such concerns and will always retain control over program content and development by always retaining authority to be the final decision maker in relation to all programs for which MSA is identified as producing.

1.4 There are a range of regulatory controls that apply to the marketing (including advertising) of medicines and medical devices in Australia. The marketing of the prescription medicines to healthcare professionals is subject to self-regulation through the '*Code of Conduct*' of Medicines Australia and failure to meet both the spirit and letter of the Code can result in a heavy penalty for the Company. Advertising of prescription medicines to consumers is prohibited in Australia. The Therapeutic Goods Administration may also apply legislative controls for non-compliance with the Code or provisions of the therapeutic goods legislation.

1.4.1 Certain over-the-counter medicines, and most complementary medicines are permitted to be advertised to both healthcare professionals and consumers in Australia. Advertising to consumers must comply with the *Therapeutic Goods Advertising Code* while to healthcare professionals with the Australian Self Medication Industry or the Complementary Healthcare Council of Australia codes of practice respectively. Self-regulatory and legislative sanctions and penalties apply for non-compliance.

1.4.2 Similar self-regulatory controls are being developed for the medical devices industry and advertising of medical devices, where permitted to consumers, is also subject to the provisions of the *Therapeutic Goods Advertising Code*.

1.5 Collaboration between the pharmaceutical and medically-related products and services industries and MSA working together on issues of common interest shall endeavour to be undertaken in accordance with the published guidelines or amendments thereto, of the Consumer's Health Forum of Australia. Relationships with pharmaceutical companies will also be guided by the Consumers' Health Forum of Australia and Medicines Australia Guide - '*Working Together – A Guide to relationships between Health consumer organisations and Pharmaceutical Companies*'.)

1.6 MSA recognises the importance of the perception and fact of fair and equal relationships with all pharmaceutical and industry organizations.

2. Respective roles and structures

MSA wishes to have co-operative relationships with the Companies through mutual respect for the aims and integrity of each party.

2.1 The Companies are expected to avoid the creation of any organisation that could give rise to confusion or conflict with the interests of MSA.

3. Use of name and trademarks (logos) of MSA.

To avoid erroneous perceptions of endorsement, any linking of the name or trademarks (logos) of MSA with Companies, their products or services must first be reviewed and approved by MSA according to these criteria:

3.1 The name(s) and trademarks (logos) of MSA are its exclusive property and may not be used without explicit prior agreement.

3.2 If so required by MSA, a Company must state that MSA has not endorsed its products or services.

3.3 Statements published in any form must be true, valid and not misleading.

3.4 In all dealings with MSA, whether the MSA name and/or trademarks (logos) is used or not, the Companies must observe and comply with, as applicable, National and State legislation, the Medicines Australia '*Code of Conduct*', *the Therapeutic*

Goods Advertising Code and related legislation and other regulations on advertising to the public, clients and healthcare professionals.

3.5 In statements that also refer to MSA, a Company cannot claim that the product is superior to or preferable to competitors' products, unless the statement is able to be substantiated as true in line with requirements of the Medicines Australia '*Code of Conduct or other applicable industry code, or the Therapeutic Goods Advertising Code (whichever Code is to apply to the product in question and the target audience (consumers of healthcare professionals) to which the claim is directed)*', and MSA confirms that it has no objection to the statement being made.

3.6 Promotional material which uses the name or trademarks (logos) of MSA, must clearly and conspicuously disclose if a Company has made a donation in money or in kind for the use of the name or trademarks (logos). The MSA name and trademarks (logos) cannot be used on promotional material for particular products.

3.7 Advertisements must make clear that support of, or contributions to, MSA by a company are not conditional upon sales of the Company's product. The MSA name and trademarks (logos) cannot be used on advertising material for particular products.

3.8 MSA will avoid, where possible, exclusive Company sponsorships but will seek joint support wherever appropriate. MSA will seek support from all Companies but will proceed, in accordance with this policy, only with those which take up the sponsorship opportunity.

4. Acknowledgements and disclaimers

MSA will, where appropriate, report donations from the Companies as part of its usual accounting and transparency arrangements. Acknowledgement of financial or in-kind support by Companies will be made for all supported programs and research. References will be to Company names rather than specific products.

4.1 Acknowledgement of financial support provided for the development, publication and distribution of print or electronic media will be agreed with Companies before publication or production. MSA will exercise the final decision about the relative prominence, size or dominance of its own trademarks or Company's logos or acknowledgements.

4.2 The following are typical acknowledgements; the exact wording will be at the discretion of MSA as appropriate:

- For MSA-originated material:
'Publication of this (booklet, etc) was made possible by an unrestricted educational grant from the XYZ Company'. (A Company logo may be included at MSA's discretion).

- For MSA-produced audio-visual material:
'Produced by MSA, supported by an unrestricted donation from the XYZ Company'. (A Company logo may be included at MSA's discretion).
- For display material at events:
'The support of XYZ Company is gratefully acknowledged'.

4.3 Where MSA provides advice in the preparation of material about multiple sclerosis for a Company, its assistance can be publicly acknowledged; however, the content should not include product identification unless the material discusses the full range of available treatments and does not focus on a particular product and is therefore educational and not promotional. A typical acknowledgement is as follows:

'Prepared with technical assistance from MSA'.

4.4 In addition to the acknowledgement, a disclaimer is also required on publications and other materials. A typical disclaimer is as follows:

'Acceptance of a donation by MSA does not constitute endorsement by MSA of any product or service of XYZ Company. MSA does not approve, endorse or recommend specific products or services but provides information to assist its clients to make their own decisions'.

5. Information exchange

MSA maintains the right to present information relating to a Company's products or activities as it feels appropriate, and will have generally relied on documented evidence and/or the advice of knowledgeable practitioners identified by it in presenting such information. MSA will retain control of the presentation of such information. It will not act as a conduit for advertising, explicit or implicit.

5.1 MSA will acknowledge support of sponsoring Companies as set out in section 4 above.

5.2 MSA welcomes provision of evidence-based information about medicines, devices or services and the trials in which they have been tested. It recognises that a Company may wish to present their products and services to the market in the best light; and MSA may seek independent verification of data where-ever possible.

5.3 MSA may produce information about specific products and services, but will always refer to other products or services of a similar nature when appropriate.

5.4 MSA may, at its absolute discretion, choose to recommend the provision of a particular product or service, but will not endorse it beyond reference to the available body of evidence including that on which a marketing authorisation or the manufacturer's claims of efficacy are based. In making any such recommendation, care will be taken to avoid a situation where MSA is seen to be advertising the particular product or service.

5.5 MSA is interested to receive advance data about services or products and trials from Companies or their authorised representatives or agents. MSA may, at its absolute discretion, pass such information to people affected by MS.

5.6 In published material in any form, MSA may draw attention to known adverse effects, including interactions, safety and side effects and will seek to ensure that such publication constitutes education, not advertising.

5.7 In accordance with National Privacy Principles, MSA will not provide its mailing lists to the Companies, but may under certain circumstances agree to circulate invitations to those on its lists to make independent contact.

5.8 Information provided by MSA to a Company must be acknowledged in publications and its use must be agreed with MSA before publication. Such information cannot be used to claim or imply endorsement by MSA.

6. Public relations, promotion and lobbying

6.1 MSA may, at its discretion, join with Companies in public relations activities relating to the provision of information about and access to products and services.

6.2 MSA may, at its discretion, participate with the Companies in political lobbying and campaigns.

6.3 MSA may, at its discretion, participate with Companies in promotion and related activities, within the limits set by current legislation, in particular the therapeutic goods legislation, and the provisions of the *'Code of Conduct'* of Medicines Australia or other applicable industry code. (See also clauses 1.3 and 5.3).

6.4 In the event that MSA joins or participates with Companies in public relations, promotions and political lobbying in support of seeking the approval for the introduction on new products, MSA will fully fund these activities from its own unrestricted resources.

7. Educational events

MSA may, at its discretion, participate with the Companies in educational activities for MSA member organisations, the health care professions and people affected by multiple sclerosis, including conferences, regional seminars, or symposia. Depending on the extent of MSA's involvement in organising such an event, it will have regard to the *'Code of Conduct'* of Medicines Australia.

7.1 MSA staff and advisers are ultimately responsible for the identification of needs, determination of objectives, content, speakers, methods and materials. Speakers may be requested, whenever appropriate, to use generic names of products rather than trade names during events, in accordance with the provisions of paragraph 1.4. Speakers are to be advised of MSA policy in regard to the use of generic names and

will be required to sign a declaration that they are aware of the policy and will indemnify MSA against any claims through their use of trade names in their presentations, either deliberate or unintentional.(See also 7.2.2 below)

7.2 Donations may be accepted in support of educational events that are developed for MSA, health care professionals and volunteers and people affected by Multiple Sclerosis, subject to the following conditions:

7.2.1 Financial support will be accepted, but only where MSA retains full control of the program, for speaker costs, travel, modest accommodation, refreshments or promotional materials. Whilst this support is acceptable, it may not be identified as a donation and may be subject to GST.

7.2.2 Speakers are expected to be aware of and may be informed by MSA in advance of the requirement for a balanced presentation about the range of therapeutic products or services. They are expected to provide accurate and unbiased information and to answer questions objectively.

7.2.3 Sales representatives may not present promotional material, other than for non-prescription medicines or other products and services, direct to clients of MSA who are people with multiple sclerosis. Sales representatives are permitted to provide educational material to clients of MSA, but MSA reserves the right to review that material before any such presentation.

7.2.4 The nature and extent of Companies' support for the program and/or speakers will be made public at meetings. Speakers should also disclose to the audience any other financial relationships they may have with sponsoring Companies.

7.2.5 Educational materials produced by MSA, such as booklets, brochures, leaflets, newsletters, posters, or videos may be written and produced with the assistance of unrestricted grants from the Companies and may be acknowledged as produced with the assistance of the Companies. Responsibility for content, selection of writers, illustrators or other contributors rests with MSA.

7.2.6 Where financial support is identified as a 'fee for service', MSA shall clearly state on any document provided to a client using that service, or in any other contact with a user of that particular Company's product that the use of the Company's product should not be construed as an endorsement of that product by MSA.

7.3 Restricted or specified donations will not be accepted from Companies by MSA for education events that include political lobbying conducted by or on behalf of Companies.

8. Company displays and materials

8.1 National or State/Territory legal or regulatory restrictions on promotion of medicines, medical devices and services must be observed by the Companies and MSA.

8.2 MSA will not agree to direct promotion or supply to consumers of medicines or medical devices requiring a physician's prescription at events taking place in, or associated with, its name.

8.3 MSA will not agree to direct promotion or supply to consumers of medicines or other products for which direct-to-consumer advertising is prohibited or access controls (through pharmacies) are required at events taking place in, or associated with, its name.

8.4 Educational material that discusses the full range of available treatments for multiple sclerosis and does not focus on a particular product, or general company information, may be made available.

8.5 MSA reserves the right to review all materials that are to be distributed by a Company at any event taking place in, or associated with, its name.

9. Research

MSA initiated basic research projects supported by the Companies must have formal approval of the MSRA Research Management Council and be ethically, socially and scientifically acceptable according to prevailing national standards. Similarly, participation of MSA in company-initiated research projects must meet the same criteria.

9.1 MSA prefers joint arrangements with more than one Company for funding or otherwise supporting research.

9.2 In particular, the Companies are encouraged to provide data to MSA that will contribute to its mission and particularly to current national and international MS research databases.

9.3 Where any commercially viable property, including intellectual property, results or may result from jointly supported research, MSA may require the Companies to agree to equity or profit sharing arrangements.

10. Confidentiality

It is the responsibility of MSA to maintain the privacy of people affected by multiple sclerosis and their professional and volunteer caregivers in accordance with the provisions in the *Privacy Act 1988*.

10.1 MSA staff and volunteers will not provide names of people affected by MS, or share or provide mailing lists to Companies without the specific approval of the legal owners of those lists.

10.2 Evaluation of events by individual participants will be anonymous except where the participant chooses otherwise.

10.3 Participants attending events organised by or in conjunction with MSA may choose to sign a company mailing list, but it will be made clear that this is not required by MSA.