IMSA GUIDELINES ON THE SUPPORT AND FUNDING OF PATIENT ORGANISATIONS

Principles

This Code should be read in the context of the following principles:

- Mutual respect & integrity
- Transparency of relationships
- Independence of organisations
- Freedom of expression
- Adherence to legislative and regulatory frameworks applicable to:
    - The marketing of medicines
    - The pricing of healthcare
    - The funding of healthcare
    - Undue influence and/or corruption and/or perversity
- The desirability of diversification of funding sources

Application of this Code

This Code applies to Innovative Medicines SA (IMSA) as an organisation and to its individual constituent members. IMSA will encourage wider acceptance and buy-in of this Code.

Preamble

The pharmaceutical industry and patient organisations often have common interests and concerns. These issues include, but are not limited to, access to healthcare, the availability of healthcare, funding mechanisms for healthcare, patient empowerment and access to information, etc. Through its research work, the pharmaceutical industry may also have specific experience and knowledge of certain disease areas. There is often a need for support for patient organisations that will enhance the objectives of the organisation in terms of empowerment of its constituents.

There is, in principle, nothing wrong with relationships that support common goals. However, such relationships have to be tailored and executed in a manner that avoids undue influence, corruption and/or perversity.

It is acknowledge that, as non-governmental and community-based organisations, many patient support and advocacy groups experience financial constraints. However, the broad funding of patient organisations from multiple sources is encouraged.

This Code provides guidelines as to how this objective can be achieved.

Guidelines -

- Relating to transparency:

1. The funder / sponsor / supporting organisations are to provide the names of the organisations they support. Such declarations will be made in their official publications of the organisation and will indicate the nature of the support (e.g. assistance with arrangements, sponsorships of events, annual financial conditional or unconditional grants, expert and other human resource support, etc).
2. It is strongly recommended that the patient organisation declare the names of all contributing organisations and the nature of the support in general and at specific events or projects.
3. Supporting- and patient organisations will, in addition to guidelines 1 and 2 disclose the names and nature of support when so requested.
4. It is advisable for patient organisations to indicate support by an organisation for specific or continuous projects or activities on the programme and/or invitation and/or publication or presentation and/or on general letterheads, email headers or footers, etc.
5. Organisations are encouraged to reduce the agreement concerning support to writing and to attach a copy of these Guidelines to such agreement (comment: one could also make this "compulsory"). Such agreement could, for example, entail details as to publicity for the supporting organisation, the nature and extent of the support, nature of interactions between the parties, dispute resolution, duration and termination, use of logo's, etc.

- Relating to independence:

6. Organisations will respect each other's independence. It is recommended that this independence be affirmed and made practical in the support agreement (e.g. that the sponsoring organisation will not dictate the operations, or ways of working of the recipient organisation, or that the sponsoring organisation will not influence the policies, programmes or activities of the recipient organisation, or that no product names or specific treatment modalities will be advanced or that speakers will be chosen, or agreed to, by the patient organisation).
7. No improper *quid pro quo* will be set in any programme or project, e.g. that support is dependent on the recipient organisation taking a particular stance in relation to medicines or treatment or that the recipient organisations embark on a specific programme or convey a specific message.
8. Supporting organisations may set conditions relating to good corporate governance, sound financial management on recipient organisations and, if applicable, a report or verification of the achievement of the objectives of the specific project that has been supported.
9. Nothing in these guidelines should be read to prevent the sharing of resources, programmes, events or the piggy-backing of one event unto another, provided that each organisations maintains its independence in terms of its views and policies, and that the financial implications of such sharing is agreed to upfront, and in line with these guidelines.
10. Where mutual events or projects are embarked upon as joint events or projects, both organisations will have equal say in terms of the nature and extent of the event or project.

- Relating to integrity:

11. Support should, in principle, not result in the exploitation or abuse of the patient organisation or its constituent members.
12. Support should, in the end, benefit the patients that the organisation seeks to assist, protect and/or empower.

13. Support should not require of the organisation to relinquish any principle held dear by it and/or its members or constituent organisations.

- Relating to freedom of expression:

14. In addition to the guidelines relating to independence, the following guidelines relate specifically to freedom of expression:

14.1 Where organisations share platforms, media or other means of expression, care should be taken to ensure that the views expressed by either party are not dictated to by the other. Speakers, authors and others involved should be informed accordingly. Materials published jointly should be signed off by both parties, by persons authorised to do so.

14.2 Any agreement that limits the expression of either party will constitute improper influence.

14.3 Distribution of materials by either organisation that are produced by the other is acceptable, provided that the source of the materials is recognised and, where such is provided free of charge, that it is recognised in terms of the guidelines on transparency, by both organisations. Statements relating to facts such as, that the views expressed in such material does not necessarily reflect the views of the distributing organisation, may enhance independence and freedom of expression.

14.4 Care should be taken to ensure that the public is clear about the roles in which persons make statements, produce information or submit comments. For example, medical practitioners, should make clear when statements are made as medical practitioners or when these are made as representatives of either a pharmaceutical company or as a representative of a patient organisation.

15. The guidelines relating to regulatory frameworks should not be read to prevent any organisation from expressing its views on the regulatory frameworks or lack thereof, or from lobbying for changes relating to such regulatory environments or the bodies that enforce or apply such regulatory frameworks.

16. Where organisations report on events, programmes or organisations, standard principles of good journalistic practice will be adhered to.

17. Information relating to diseases, treatment and lifestyle has to be factual, verified, balanced (i.e. include both positive and negative aspects), realistic and include references to sources used in its compilation. These sources should include credible, objective source material. It is advisable that there is an identified person to whom queries on the information provided may be directed.

- Relating to existing legislative and regulatory frameworks:

18. No agreement, activity or programme, whether explicit or implicit, may amount to a breach of any existing regulatory framework or professional code of conduct, including, but not limited to –

18.1 The Medicines and Related Substances Act and its accompanying sets of regulations (General Regulations and Pricing Regulations), specifically those provisions relating to bonusing, sampling and donations; the SEP-system; the marketing, promotion and advertising of medicines; etc.

18.2 The Medical Schemes Act and its accompanying regulations, in particular those relating to the establishment and business of a medical scheme; agreements relating to DSPs; the establishment and enforcement of formularies; scheme rules, etc.

18.3 The legislation and Codes of Conduct relating to the professions, including but not limited to those applicable to medical practitioners and pharmacists, such as the Perverse Incentives Policy and the Undesirable Business Practices Policy.

18.4 The Prevention and Combating of Corrupt Activities Act, that prohibits the general offence of corruption, i.e. the provision of any benefit in return for certain behaviour or

influence, that amounts to behaviours that is illegal, dishonest, unauthorised, incomplete, or biased; or the misuse or abuse of power or trust.

Enforcement

Adherence to this Code is voluntary, but members of Innovative Medicines SA are, by virtue of their membership to IMSA, bound by this Code. IMSA and its member companies may require that agreements and negotiations preceding agreements incorporate this Code.
