Guidelines[1] for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization

Introduction

IFPMA members:

Supporting the objectives of the Convention on Biological Diversity (CBD) and recognizing the national sovereignty of States over biological resources,

Supporting and wishing to participate in the development of a regime on Access and Benefit Sharing (ABS), which would facilitate the sustainable use of genetic resources (GR) and, once clearly defined, associated traditional knowledge (TK) and regulate the rights and responsibilities of users and providers of such resources in a transparent way, taking into account related discussions and outcomes from other relevant international fora,

Aware of the important role the research-based pharmaceutical industry has to play as a stakeholder in informing policy decision-making related to this issue through its unique expertise and practical experience in managing the complex nature of the medical innovation process,

Willing to participate in appropriate technical assistance, in coordination with the CBD Secretariat and CBD parties/observers or other appropriate organizations, to build the legislative, science and negotiating capacity of CBD parties,

Calling on CBD members to ensure continuing education and outreach efforts to facilitate capacity building, either independently or through a body such as WIPO, relating to the development of model and/or national legislation governing prior consent and benefit sharing laws, including model clauses for ABS agreements, keeping in mind that such laws should achieve a satisfactory balance between the conservation of biodiversity and encouragement of access to and use of GR in a way that would promote fair and equitable benefit sharing,

Propose concrete measures to facilitate implementation of CBD provisions relating to access to genetic resources and equitable sharing of the benefits arising out of their utilization and related traditional knowledge.

Objective

International research-based pharmaceutical companies support a positive approach to CBD implementation consistent with other international obligations and agreements. Successful resolution of issues raised in various fora concerning Access and Benefit Sharing will enable industry to facilitate implementation of CBD provisions relating to access to genetic resources[2], and equitable sharing of the benefits arising out of their utilization and reasonably related and clearly defined forms of traditional knowledge[3] in the context of (i) CBD obligations on states to facilitate access and not impose restrictions on access that run counter to CBD objectives and (ii) the CBD recognition that access and benefits sharing should be on mutually agreed terms.

[1] The Guidelines list certain "best practices" which should be followed by companies which will engage in the acquisition and use of genetic resources.

[2] Under the CBD, Conference of Parties COP Decision II/11, para. 2, human genetic material is excluded from the scope of the CBD. In addition, materials removed from in situ locations prior to 1992 also fall outside the remit of the CBD.

[3] As recognized by the recent European Community and Member States Proposal to WIPO: "there are concerns about the possibly unclear scope of the term 'traditional knowledge'. In order to achieve the necessary legal certainty, a further in-depth discussion of the concept of TK is necessary." Source: http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf

International Federation of Pharmaceutical Manufacturers & Associations
Ch. Louis-Dunant 15
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org

IFPMA

The following provides an outline of industry best practices and steps that CBD members should take in order to provide the legal environment necessary to allow such best practices.

Industry Best Practices

1. To obtain prior informed consent (PIC) to the acquisition and use of genetic resources controlled by a country/indigenous people and provided to the company in accordance with local law.

2. In obtaining PIC, to disclose the intended nature and field of use of the genetic resources.

3. To gain necessary approval to remove materials found *in situ*, and to enter into formal contractual benefit-sharing agreements reflecting the mutually agreed terms (MAT) on the use of the genetic resources obtained through that removal. These agreements may contain conditions on permissible uses of the genetic resources, transfer of the genetic resources to third parties, and appropriate technical assistance and technology transfers.

4. To avoid taking actions, in the course of use or commercialization of genetic resources obtained as specified under these commitments that impede the traditional use of such genetic resources.

5. To agree that any disputes as to compliance with the clauses contained in formal contractual benefit-sharing agreements are dealt with through arbitration under international procedures or as otherwise agreeable between the parties.

Enabling Steps by Government

1. Actual enactment of national legislation implementing the CBD.

2. Establishment of Focal Points.

Such national focal points should establish clearly which indigenous groups or other stakeholders possess rights to authorize access to particular genetic resource(s) *in situ* within any CBD member.

This would provide transparency and legal certainty to industry and to other interested parties. Such focal points may wish to establish databases recording the existence of genetic resources and its uses.

3. Commitment to enter into good faith negotiations as to the terms of access and benefit sharing contracts with commercial entities.

4. Agreement on dispute resolution as outlined in point 5) above.

Conclusion

IFPMA members strongly believe that implementing this agenda will significantly contribute in achieving to establish a practical access and benefit sharing environment conducive to value creation and equitable sharing of rewards through the clarification of major stakeholders respective rights and responsibilities.

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