CODE OF CONDUCT FOR THE RELATIONS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENTS' ASSOCIATIONS, PATIENTS ADVOCATES, PATIENTS EXPERTS, PATIENTS AND CAREGIVERS

Since 1999 APIFARMA - Associação Portuguesa da Indústria Farmacêutica has a Partnership with Portuguese Patients' Associations, with the aim of cooperating in supporting the needs of patients and/or caregivers.

In order to ensure that relations between the Pharmaceutical Industry and Patients' Associations take place in an ethical and transparent manner, EFPIA, the European Federation of Pharmaceutical Industries and Associations, approved in October 2007 a Code of Conduct for Relations between the Pharmaceutical Industry and Patients' Associations. This Code was adapted for Portugal and has been in force since then and was subject to a review in 2011 because of a joint update by EFPIA with the pan-European patients' organisations.

Over the last decade the intervention of Patients' Associations at European and national level has grown, and turned them into privileged interlocutors of companies and community institutions, both governmental, such as the European Commission and the European Parliament, and regulatory, such as the European Medicines Agency, as well as national institutions, such as, for Portugal, INFARMED, I.P., Autoridade Nacional do Medicamento e Produtos de Saúde, I.P..

The growing relevance of Patients' Associations and the constant interaction with pharmaceutical companies has shown the need to revisit, at European level, in a first instance, the Code of Conduct with Patients' Associations.

EFPIA approved at the General Assembly of June 27th 2019 a new EFPIA Code of Practice which incorporates the ethical rules of interaction between companies and Patients' Associations, and which APIFARMA now adapts to the relations between its member pharmaceutical companies and the Patients' Associations based in Portugal.

The opportunity is taken to adopt some ethical solutions included in the Code of Practice of IFPMA, International Federation of Pharmaceutical Manufacturers & Associations, 2019.

This new Code is inspired by the fundamental principle that people with diseases are at the core of pharmaceutical companies' activities and that all their activity should be to the benefit of patients.

This Code regulates, for the first time, the possibility for APIFARMA member pharmaceutical companies to cooperate with Patient Advocates, Patient Experts, Patients and Caregivers, due to the experience and knowledge they have in defending and supporting patients, for their technical-scientific knowledge and roles in the area of research, development, regulatory affairs or for their privileged knowledge of the disease, for living or caring for those living with it.

This cooperation should be mediated by Patients' Associations, which are and will continue to be the privileged point of contact for companies in the pharmaceutical industry for the purpose of cooperating with Patient Advocates, Patient Experts, Patients and Caregivers. However, direct hiring of Patient Advocates is allowed, although such contact should be made through the Patients' Associations if they are members or associates of the latter. The same situation is not allowed when it comes to the relationship with Patient Experts, Patients and Caregivers, where any cooperation will necessarily have to be mediated and contracted through the Patients' Association, unless there is no Patients' Association for a particular pathology or therapeutic area.

In order to achieve the goals set out in this Code, APIFARMA's member pharmaceutical companies undertake to pursue the following principles in their relations with Patients' Associations Patient Advocates, Patient Experts, Patients and Caregivers (hereinafter referred to as "Partners"):

1. the principle of independence of Partners with regard to their decisions, institutional choices and activities;
2. the principle of integrity, acting responsibly and ensuring that their interventions and communications are accurate, legitimate and balanced;
3. the principle of mutual respect and reciprocity, the views and decisions of each Partner being equally appraised;
4. the principle of diversified funding of Patients' Associations by multiple pharmaceutical companies and other entities as a means to safeguard the independence and credibility of all parties;
5. the principle of transparency in all activities and relationships established, including the disclosure of all benefits in kind or in cash granted, directly or indirectly, to the Partners;
6. the principle of privileged contact with Patients' Associations for the purpose of cooperating with Patient Advocates, Patient Experts, Patients and Caregivers.

The rules established herein were freely discussed and voluntarily accepted and are binding for all APIFARMA Member Companies.

Chapter I

Scope and definitions

Article 1

Scope

1. This Code of Conduct aims to define a set of rules governing the relations between APIFARMA member Pharmaceutical Industry companies that market prescription and non-prescription-only medicinal products, and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers.

2. The rules included in this Code are binding for all APIFARMA member companies that market prescription and non-prescription-only medicinal products, and for their employees in their professional relations with Patient's Associations, Patient Advocates, Patient Experts, Patients and Caregivers.

Article 2

Definitions

1. For the purposes of this Code of Conduct there are the following concepts:

a) *Support* - a contribution, financial or in kind, granted by a company to a Patients' Association for the development of an event and/or activity of its initiative and responsibility, without any compensation for the company.

b) *Patients' Associations* - non-profit organisations which comprise mainly patients and/or caregivers, representing and/or supporting the needs of patients and/or caregivers and which operate in Portugal.

c) *Personal benefit* - any benefit, regardless of its amount, that is not related to a legitimate activity under the provisions of the APIFARMA Code of Ethics or the current legislation.

d) *Contract for the Supply of Services* - a contract whereby one of the parties undertakes to provide the other with a certain result of its intellectual or manual work, with or without payment.

e) *Caregiver* - an individual who accompanies and takes care of the patient, whether he or she is a family member and/or friend of the patient, a volunteer or a person hired to carry out this activity. When he/she represents the Patients' Association to which he/she is affiliated, he/she appears as the *Representative of a Patients' Association.*

f) *Patient*- a person living with a disease. For the purposes of this Code, he/she only represents him/herself and his/her opinion/experience as a patient, regardless of his/her technical knowledge in research and development and/or regulatory affairs. When he/she represents the Patients' Association to which he/she is affiliated, he/she appears as the *Representative of a Patients' Association.*

g) *Member Companies* - companies in the pharmaceutical industry which are members of APIFARMA and which market prescription and non-prescription-only medicinal products, sometimes referred to, in short, as "companies" for the purposes of this Code.

h) *Hospitality* - logistical support provided by pharmaceutical companies to representatives of Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers, for the purpose of participating in events and activities organised by the companies themselves and/or by third parties, namely by supporting the cost of meals, travel, accommodation and registration.

i) *Medical Utility Items* - objects intended to provide health care to the patient, not related to the promotion of medicinal products, relevant to the activity of the Healthcare Provider and which may contribute to help the patient in the administration of the medicine and/or in the management of the disease. These objects should not consist of personal benefits for the Healthcare Provider, nor should they correspond to objects that the Healthcare Provider normally acquires as part of his/her daily work (e.g. office supplies, gloves, stethoscopes, sphygmomanometer).

j) *Gift*- benefit in kind that does not constitute an item of medical utility, information, or educational material.

k) *Partnerships* - cooperation between one or more Member Companies and one or more Patients' Associations for the development of a specific project (event or other activity), under the responsibility of both parties, limited in time and scope. In a partnership both parties have specific and documented responsibilities and both draw a legitimate benefit from the implementation of the project.

l) *Patient Advocate* - a person with knowledge and experience in the defence and support of a population of patients living with a certain disease. He/she may or may not be affiliated with a Patients' Association.

m) *Patient Expert* - a patient with technical knowledge in research and development and/or regulatory affairs, by virtue of his/her experience and/or training. For the purposes of this Code, he/she only represents him/herself and as an "expert" in research and development and/or regulatory affairs.

n) *Sponsorship* - a contribution, financial or in kind, granted by a company to a Patients' Association for the development of an event and/or activity of its initiative and responsibility, and which involves a compensation to the company.

o) *Relations between Pharmaceutical Industry companies and Patients' Associations:* any interaction between these entities, including the allocation of funds by a Company to a Patients' Association.

p) *Representative of a Patients' Association:* a person empowered to represent and express the collective vision of the Patients' Association he/she represents, on a given topic or therapeutic area

Chapter II

Relations between the Companies, Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers

Article 3

General rules

1. The relations of APIFARMA member pharmaceutical companies with Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers are based on the fundamental principle that people with a disease are at the core of the pharmaceutical companies' activities, as well as the other ethical principles referred to in the Preamble of this Code.

2. The relations referred to in the preceding paragraph may not, directly or indirectly, constitute an incentive to recommend, prescribe, market, purchase, sell or administer any medicinal product or any other pharmaceutical product.

Article 4

Promotion of prescription-only medicinal products

The promotion of prescription-only medicinal products to Patients' Associations, their representatives, Patient Experts, Patient Advocates, Patients or Caregivers who are not healthcare providers is prohibited.

Article 5

Information on prescription-only medicinal products

1. The scientific areas of the companies can, upon written request of the Patients' Associations, make available, to healthcare providers who cooperate with them, information on advances in the area of medicinal products and therapeutics.

2. The scientific areas of companies may, upon written request, provide information on marketed medicinal products, in accordance with the legislation in force on the advertising of medicinal products.

Article 6

Written Agreements

1. All partnerships, services supply and financial support or sponsorships granted by the Companies to Patients' Associations should be made in writing, through agreements signed by both parties before the beginning of their respective activities, which include the minimum requirements provided for in the Code and in the respective contractual models annexed to the Code.

2. Support in kind granted by the Companies to Patients' Associations worth more than € 60.00 should be made in writing, and the respective agreement should include the minimum requirements set out in this Code and in model A annexed to the Code.

3. The services supply contracted by the Companies to Patient Advocates, Patient Experts, Patients or Caregivers under the provisions of Articles 9 and 10 are also the subject of written agreements, signed before the start of the provision of services, which must include the minimum requirements set out in models B and C annexed to this Code.

4. Each Company shall set up an internal procedure for the formal approval of the agreements referred to in the previous paragraphs.

5. Invitations by companies to participate in events organised by them and by third parties need not be the subject of a written agreement between the parties but should be formalised in writing.

Article 7

Use of logo and materials subject to copyright

1. The use by a Company of a logo, name and/or copyrighted materials belonging to a Patients' Association is subject to prior written authorisation by the latter.

2. The application for authorisation referred to in the preceding paragraph should clearly state the specific purpose and the way in which the logo, name and/or copyrighted materials are used by the Company.

Article 8

Financing of Patients' Associations

Companies may not ask or require to be the exclusive financing entity of a Patients' Association or of any of its activities or events.

Chapter III

Events and activities organised by the Companies

Article 9

Provision of services by Patients' Associations to Companies

1. Patients' Associations may provide services to Member Companies aiming at supporting health, research and/or education.

2. The provision of services must comply with the following requirements:

a) written agreement must be signed before starting the provision of the services and should include the minimum requirements set out in model B annexed to this Code.

b) the existence of a legitimate need to provide these services, clearly identified and documented by the Company before the request of the service and the signature of the corresponding written agreement;

c) the criteria used in the selection of the service provider should be directly related to the legitimate need identified in the previous subparagraph and the people responsible for the selection of the service provider should have the necessary experience and knowledge to assess whether the service provider meets those criteria;

d) the number of service providers to be hired should not exceed what is necessary to meet the identified needs;

e) the length/duration of the service provided cannot be greater than what it is reasonably necessary to meet the identified needs;

f) the contracting Company should keep a record of all documentation related to the services provided and make appropriate use of this information;

g) the provision of services may not be aimed at the academic or professional training of the service provider;

h) the payment for services provided should be reasonable and reflect the market practice;

i) the contracts must include the obligation for Patients' Associations and their representatives to declare that they provide paid services to a Company whenever they write or speak in public on the matters covered by the contract or on matters relating to the Company;

j) the Companies may not use the activity of providing services to try, directly or indirectly, to influence the decisions, positions, or opinions of the service provider.

Article 10

Provision of Patient Advocates' services to the Companies

1. Member Companies may use the services of Patient Advocates with the purpose of supporting health, research and/or education.

2. Notwithstanding the provisions of the preceding paragraph, whenever the Patient Advocate is a member or associate of a Patients' Association operating in the therapeutic area or pathology to which the provision of services refers, the respective contact should be made through the Patients' Association.

3. The provision of services with Patient Advocates must meet the requirements set out in no. 2 of Article 9 and be the subject of a written agreement that includes the minimum requirements set out in model C annexed to this Code.

Article 11

Providing Patient Experts, Patients and Caregivers' services to the Companies

1. Member companies may only use the services of Patient Experts within their research, development and/or regulatory activities and of Patients and Caregivers if these services are aimed at improving knowledge about the personal experience of the Patient and/or his/her Caregiver.

2. The services referred to in the previous number must be carried out and contracted through the Patients' Association, which also selects the Patient Expert, the Patient and the Caregiver.

3. When there is no Patient Association operating within a given pathology or therapeutic area, the Member Companies may, exceptionally, hire directly Patient Experts, Patients and Caregivers for the purpose of providing the services set out in number 1, provided they act in compliance with the provisions of this Code and the legislation in force.

4. The contracts for the provision of services referred to in the previous numbers should comply with the requirements provided for in no. 2 of Article 9 and include the minimum requirements set out in model B annexed to this Code.

Article 12

Events organised by the Companies

1. Any event organised by a Company, with the participation of representatives of Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers, cannot be of a promotional nature and must be held in a venue suitable for the main purpose of the event.
2. When holding events, the Companies should not choose venues and/or developments that are known as leisure, entertainment, or sports facilities.

3. The events referred to in the previous numbers should be held in Portugal, unless it makes more logistical sense to hold the event in another country:

a) taking into account the countries of origin of most of the guests; or

b) taking into account the location of the relevant resources or knowledge, which constitute the object or topic of the event.

4. When events organised by the Companies take place in another country, the rules of this Code and the rules of the Code of Ethics in force in the country where the event takes place must be complied with, and in case of conflict the most restrictive rule should prevail.

Article 13

Support granted by Companies for the participation in events

Member Companies may support in the form of hospitality the participation of representatives of Patients' Associations, Patient Experts, Patient Advocates, Patients and Caregivers in institutional, scientific and/or educational events organised by the Company itself or by third parties, as long as they comply with the rules set up in this Code.

Article 14

Hospitality

1. The hospitality provided by the Companies must meet the following requirements:

a) to be of a reasonable quality level and strictly limited to the main purpose of the event;

b) to be restricted to travel, meals, accommodation and registration costs and be limited to the participants in their own right;

c) should not include the organisation of events of entertainment nature (e.g. leisure, entertainment or sports);

d) should not exceed the period from the day before the start to the day after the end of the event;

e) should not be provided as compensation for the time spent by guests in attending the events.

2. In the event of a clear need to assist the participant or the service provider, the Companies may bear the costs of travel, meals, accommodation and registration of the accompanying person as the patient's caregiver.

3. The cost of meals provided to participants shall not exceed €60.00 for events taking place in national territory and €90.00 for international events, unless in the country where the event takes place the Code of Ethics or national legislation set a different amount, in which case that amount shall apply, regardless of whether it is higher.

Article 15

Gifts and Items of Medical Utility

1. Member companies may not directly or indirectly provide gifts to Patients' Associations, their representatives, Patient Advocates, Patient Experts, Patients or Individual Caregivers.

2. Associated companies are also not allowed to provide the persons and entities referred to in the previous paragraph, as personal benefit, with cash or equivalent and services.

3. Companies may only assign, permanently or temporarily, items of medical utility to the persons who are healthcare providers, under the terms and for the purposes of the "APIFARMA's Code of Ethics for Pharmaceutical Industry Promotional Practices and for Interactions with Healthcare Providers and Institutions, Organizations or Associations constituted by Healthcare Providers".

Article 16

Information or Educational Materials

The Member Companies may provide information or educational materials to Patients' Associations intended for Patients, Caregivers and the general public, regardless of its format (paper or digital), provided that, cumulatively:

a) its unit value is less than EUR 60.00 (VAT included);

b) its content is relevant to Patients, Caregivers and the general public;

c) it has no direct or indirect reference to a prescription-only medicinal product, and

d) the relevant legal provisions are complied with.

Chapter IV

Events and activities co-organised by Companies and Patients' Associations

Article 17

Partnerships between Companies and Patients' Associations

1. Companies and Patients' Associations may build partnerships that are based on a legitimate and common interest and that are developed, planned and implemented with the contribution of the parties, and in accordance with their legitimate interests.
2. Partnerships may involve one or more Member Companies and one or more Patients' Associations and should always be supported by a contract with detailed information on the project and the responsibilities involved for each Party.
3. Partnerships can be built for the development of specific projects, with activities and tasks time-limited and assigned to each of the parties.
4. For the development of the projects a schedule should be established with the implementation steps, regular project compliance checks and, at the end, a joint assessment and final reconciliation of activities and costs should be done.
5. Companies may bear the direct costs of the project in their entirety but should not include costs associated with the operational costs of the Patients' Association itself or other costs not associated with the mentioned project.

Chapter V

Events and activities organised by Patients' Associations supported by pharmaceutical companies

Article 18

General requirements for Support and Sponsorship granted by the Companies

1. The member companies can support, or sponsor events and activities organised by Patients' Associations, provided that the main goal is professional, educational, scientific or to support the mission of the Patients' Association, namely, to support the needs of patients and/or caregivers and to defend their interests.

2. The support or sponsorship by companies of events or activities organised by the Patients' Associations, under the provisions of the previous article, must comply with the following conditions:

a) The Patients' Association must send a written request to the Member Company, specifying the scope and purpose of the activity or event, as well as the associated costs;

b) Companies can only bear the real, documented, reasonable and direct costs necessary to hold the event, activity or mission of the Association;

c) The Companies may not support, or sponsor leisure or entertainment activities organised by the Patients' Associations;

d) Support and sponsorship of events and/or activities must be granted to Patients' Associations and not to their individual representatives;

e) The support or sponsorship may consist of a financial or non-financial contribution, in particular the provision of logistical support for the event or the translation, proofreading and publication of materials, always in compliance with the provisions of Article 17;

f) The compensation for the sponsorship of the events, where applicable, should constitute a tangible benefit. The mere display of the Company's logo on the event's promotional materials or the award of honourable mentions of gratitude by the Association, whether written or verbal, does not constitute a tangible benefit.

3. Any financial support or sponsorship, regardless of its amount, as well as any support in kind granted by Companies to Patients' Associations worth more than € 60.00, should be set out in writing, based on model A annexed to this Code.

4. The support or sponsorship granted within the scope of events or activities of Patients' Associations must show in all promotional documentation relating to them, as well as in the documentation of the participants and in the reports or information materials disseminated or published after the events or activities have taken place.

5. The Member Company granting the support or sponsorship must keep all documentation related to it for the period laid down by the provisions in force.

Article 19

Materials produced by Patients' Associations

1. Companies should not seek to influence the content of the materials produced by the Patients' Associations they sponsor in such a way as to favour their own business interests.

2. The obligation set out in the previous number does not prevent companies from correcting factual and/or scientific inaccuracies in the materials produced.

3. By written request of the Patients' Associations, companies can cooperate in the preparation of scientific or educational texts.

Chapter VII

Transparency

Article 20

Obligation to disclose

Member Companies should publicly disclose any benefits in kind or cash which they grant to all entities and natural persons covered by this Code.

Chapter VIII

Breach of the Code

Article 21

Infringement of the Code

1. The implementation of the rules of this Code is supervised by the APIFARMA's Ethical Board.

2. In the event of a breach of the rules set out in this Code being identified, the complaint shall be referred to the Ethics Board, following the procedural steps provided for in the Regulation of the Ethics Board.

3. Violation of the rules of this Code by a Company is considered to be an ethical infringement and the sanctions provided for in the Articles of Association of APIFARMA are applied.

4. The penalty imposed and the nature of the infringement are published by APIFARMA.

Approved at the APIFARMA General Assembly of December 10th, 2020

Entry into force on January 1st 2021.

Annex I

WRITTEN MODEL AGREEMENTS BETWEEN MEMBER COMPANIES OF THE PHARMACEUTICAL INDUSTRY AND PATIENT'S ASSOCIATIONS OR PATIENT ADVOCATES

Model A - Support or Sponsorship (Financial or in Kind) granted to Patients' Associations
(Articles 6 and 18 of the Code)

a. **Essential requirements to be included in the written agreement:**
   1. Identification of the parties (Pharmaceutical Industry Company and Patients' Association);
   2. Type and form of support: support or sponsorship; financial or in kind;
   3. Description of the event or activity to be supported/sponsored and its purposes;
   4. Purpose of the support granted;
   5. Amount of funding to be granted and any associated concessions (in the case of sponsorship) or, if the support is in kind, description and respective amount (if more than EUR 60.01);
   6. Duration;
   7. Personal Data Protection Clause, as applicable;
   8. Transparency Clause (including reference to the fact that the Pharmaceutical Industry Company will disclose to the public the support granted to the Patients' Association, in accordance with the provisions of the law and art. 20);
   9. Signature of the legal representatives of the Parties involved in the support/financing;
   10. Date of the agreement.

b. Contractual Model Proposed by APIFARMA

This model comprises the essential aspects to be included in a written agreement concerning support or sponsorship granted by member companies to Patients' Associations under the terms of Articles 6 and 18 of this Code. The companies may use this model in its entirety or adapt it to the specific case, as long as they comply with the essential requirements listed above.

Location, *Date*

PARTIES:

I. COMPANY X, having its registered office at [******], with the single registration and legal person number ******, hereby represented by [insert legal representative name] as [*******], mandated for the purpose, hereinafter referred to as "COMPANY";

II. PATIENTS' ASSOCIATION Y, having its registered office at [********], and its single registration and legal person number [******], hereby represented by [insert legal representative name] as [*********], mandated for the purpose, hereinafter referred to as "ASSOCIATION" or "PATIENTS' ASSOCIATION;

The COMPANY and the Association shall hereinafter jointly be referred to as the "Parties".

WHEREAS:

I. The Company carries out its activity in the area [*describe the area of activity of the Company*];

II. The purpose of the Association is [*describe the object of the Association*];

III. The Association intends to develop [describe event/activity that the Association intends to develop] having requested the support of the Company under the terms set out in the letter of request attached to this Agreement [attach letter/e-mail sent to the Company by the Patients' Association

requesting the support];

OR

The Association intends to implement an activities plan attached to this Agreement during the year 202* [attach the activities plan that the Association intends to implement and develop], having requested the support of the Company under the terms set out in the letter of request attached to this Agreement [attach letter/e-mail sent to the Company by the Patients' Association requesting the support];

IV. The Company intends to provide support to the above-mentioned event/activity/ activities plan.

This written Agreement (the "Agreement"), consisting of the above-mentioned Recitals and the following Clauses, which the Parties undertake to abide by promptly and fully, is signed and mutually accepted:

1. PURPOSE

The purpose of this Agreement is to govern the relations between the Company and the Association within the scope of the support/sponsorship that the Company intends to provide for the implementation of the event/activity described in the Recitals of this Agreement (the "**Programme**").

2. NATURE OF THE SUPPPORT

2.1. The support that the Company provides to the Programme (the "**Support**") will be governed and implemented in accordance with the following details:

Event/Activity to be financed	
Date and Location	
Goals of the Programme that is the object of the Support	
Purpose of the Support	
Amount of funding and/or Description and amount of in-kind support	
Concessions associated with the sponsorship (if applicable)	

2.2.1. The Association undertakes to ensure that the Support provided by the Company is used solely and exclusively for the purposes and under the terms described in this Agreement.

2.3. The support provided by the Company to the Programme should be transferred to the Association's bank account within [*******] days of the date on which the invoice is received by the Company, according to the details below:

Association's Bank Account Details	
Account holder' name	
Account Holder's address	
Name of the Bank	
IBAN	

Account Currency	EURO

3. DURATION

3.1. This Agreement should remain in force for the period necessary to implement the support to the Association and should cease to have effect upon the former is provided, notwithstanding the full compliance with the obligations which may continue at the date of termination.

3.2. Either Party may terminate the Agreement at any time by written notice of [******] [in full] days by registered letter with acknowledgement of receipt addressed to the other Party.

3.3. In the event that the Company ceases, for any reason, the Programme under Support, it must notify such circumstance to the Company and all funds that have been transferred but not used within the scope of the Programme activities should be returned to the Company within a maximum of period [******] days.

4. INDEPENDENCE

4.1. The Company hereby undertakes not to influence or control the content of the materials produced by the Association and supported by the Company within the scope of this Agreement in such a way as to favour its commercial interests.

4.2. The Parties recognise that the Association has no obligation, under this or other Agreements, to promote or encourage the acquisition, use, marketing, recommendation, purchase, sale, administration and/or promotion of products marketed by the Company.

4.3. The Parties acknowledge that the Company has not requested or required to be the exclusive financing entity of the Association or of any of its activities or events, including that relating to the Programme which is the object of this Agreement.

4.4. The Company and the Association should act as independent contracting parties and no provision in this Agreement should be construed as creating any legal relationship of employment or subordination between the two Parties.

5. INDUSTRIAL AND INTELLECTUAL PROPERTY RIGHTS

5.1. The signing of this Agreement should not aim at transferring any intellectual property rights.

5.2. Notwithstanding the provisions of no. 1 of Article 159 of the Medicinal Product Statute, the public use of the logo, name and/or copyrighted materials belonging to the Association and/or the Company within the scope of the supported activities shall be subject to the written authorisation of both Parties and the application for use should clearly state the specific purpose and how the logo, name and/or copyrighted materials are used by the Parties.

6. TRANSPARENCY

The Association expressly acknowledges that the Company conveys, under the terms and by the means provided for in the applicable legal, regulatory and ethical rules, including the Medicinal Product Statute and the APIFARMA Code of Conduct for the Relations between the Pharmaceutical Industry and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers, the information relating to this Agreement that it is obliged to disclose, namely, the name and contact details of the Association, the purpose of this Agreement and any amounts paid under the latter.

7. CONFIDENTIAL INFORMATION

[To be defined by both Parties, where applicable]

7.1. The Parties undertake to keep confidential any information to which they have access or receive from the other Party relating to Intellectual and Industrial Property, know-how, trade secrets, data and files (the "*Confidential Information*").

7.2. The Parties undertake not to disclose Confidential Information and should only use Confidential Information of the other Party for the purpose of complying with their obligations under this Agreement.

7.3. The obligation under this clause does not apply to information which (i) is in the public domain (except where it is in the public domain as a consequence of non-compliance with this Agreement); (ii) is known to the other Party prior to the signing of this Agreement in a lawful manner and without being subject to obligations of confidentiality; (iii) when they must be disclosed in order to comply with a legal or administrative order or pursuant to applicable industry codes.

8. COMPLIANCE WITH LEGAL, ETHICAL AND REGULATORY STANDARDS

The Association and the Company undertake to implement this Agreement in strict compliance with all applicable laws, regulations and codes of conduct including, but not limited to, APIFARMA's Code of Conduct for the Relations between the Pharmaceutical Industry and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers.

9. DATA PROTECTION

9.1. The collection and processing of personal data of employees and representatives of the Association and the Company provided under this Agreement, are necessary for the signing and management of this Agreement and for the fulfilment of legal obligations and are therefore collected under these grounds.

9.2. The personal data of employees and representatives of the Association may be conveyed by the Company to (i) subcontractors hired by it for the purpose of processing the data, as well as to (ii) entities in which it has an interest within the above scope. In this context, data may be conveyed outside Portugal including to countries outside the European Union the legislation of which does not provide adequate security guarantees under Portuguese and European data protection legislation [TO BE ADAPTED TO THE SPECIFIC CASE ACCORDING TO THE PERSONAL DATA TRANSFER LOCATION]. The Company may also convey the personal data of employees and representatives of the Association, under the applicable and necessary terms, to the competent authorities and institutions - such as INFARMED, I.P., and APIFARMA - for the purpose of complying with legal, regulatory and/or ethical obligations applicable to the Company.

9.3. The employees and representatives of the Association, as owners of the personal data, may, through the Association, exercise the rights of access, rectification, cancellation, limitation and portability in relation to the personal data included in the aforementioned file, as well as oppose the

processing, under the terms and with the scope provided for by the applicable laws and, in particular, to revoke the consent provided, by sending a written request to the Company via e-mail [******].

9.4. The Association has the right to complain to the national supervisory authority (National Commission for Data Protection - www.cnpd.pt).

10. APPLICABLE LAW AND JURISDICTION

10.1. All matters arising from this Agreement, namely its interpretation, validity, effectiveness or implementation, should be governed and regulated by Portuguese law, which shall apply.

10.2. Any references to legal provisions or instruments should include those provisions and instruments, which tacitly or expressly will amend, revoke or reinstate them.

10.3. Any dispute arising from the interpretation or implementation of this Contract, and on which the Parties are unable to reach an agreement, should be submitted to the jurisdiction of the District Court of [********], with express waiver of any other.

11. GENERAL PROVISIONS

11.1. All communication between the Parties concerning this Agreement should be in writing, either by letter, fax or e-mail, and should be sent to the addresses mentioned at the beginning of this Contract.

11.2. This Agreement represents the full agreement between the Contracting Parties regarding the Support. No other verbal or written agreements have been adopted, which, if any, are set out in this document.

11.3. Any amendments and/or additions to this Agreement should be in writing.

Done and signed at the above-mentioned date and location in two (2) copies, one copy being destined for each of the Parties.

COMPANY	PATIENTS' ASSOCIATION
_____	_____
(LEGAL REPRESENTATIVE)	(LEGAL REPRESENTATIVE)

Model B - Services provided by Patients' Associations to Companies (Articles 6 and 9 of the Code)

a. **Essential requirements to be included in the written agreement:**
   1. Identification of the parties (Pharmaceutical Industry Company and Patients' Association);
   2. Need for the Company providing services and identification of the services to be hired;
   3. Payment and payment conditions for services rendered;
   4. Duration;
   5. Personal Data Protection Clause, as applicable;
   6. Transparency Clause (should mention the fact that the Pharmaceutical Industry Company will publicly disclose the amounts paid to the Patients' Association, in accordance with the provisions of the law and art. 20);
   7. Obligation of the Patients' Association to declare that it provides paid services to the Company, whenever it writes or speaks in public on matters covered by the contract or on matters relating to the Company;
   8. Signature of the Parties involved in the provision of services;
   9. Date of the agreement.

b. **Contractual Model Proposed by APIFARMA**

   This model sets out the essential aspects to be included in a written agreement in accordance with Article 9 (*Provision of Services by Patient Organisations to Companies*) and Article 11 (*Provision of Services by Patient Experts, Patients and Carers to Companies*). Companies may use this model in its entirety or adapt it to a specific case, as long as they comply with the essential requirements listed above.

Location, *Date*

PARTIES:

III. **COMPANY X,** with its registered office at [*******], and its single registration and legal person number [******], hereby represented by [*insert legal representative name*] as [******], mandated for the purpose, hereinafter referred to as "**COMPANY**";

IV. **ASSOCIATION Y,** with its registered office at [*******], and its single registration and legal person number [*******], herein represented by [*insert legal representative name*] as [******], mandated for the purpose, hereinafter referred to as **"ASSOCIATION"**;

The **Company** and the **Association** shall henceforth be referred to just as "Party" when referred to individually and as "Parties" when referred to jointly.

WHEREAS:

I. The Company carries out its activity in the area [*description of the area of activity of the Company*);

II. The purpose of the Association is [*description of the corporate object of the Association*];

III. The Company wishes to hire the services of the Association, so that the latter can render the following services defined in clause 1;

IV. (TO BE USED IF THE SERVICE IS IMPLEMENTED BY A PATIENT/CARER/ PATIENT EXPERT/PATIENT ADVOCATE SPECIFICALLY) The Association, being the only entity responsible for selecting a qualified Speaker/Consultant/ Expert with the knowledge and experience necessary to render the services described in clause 1, appoints the PATIENT EXPERT/PATIENT ADVOCATE/PATIENT/ CARER, identified by Citizen's Card number (*****], living in [*********], hereinafter referred to as "**CONSULTANT**"/"**SPEAKER**"/"**EXPERT**" to carry out the effective provision of the services set out in this Contract;

The Parties, for the reasons set out above, the content and sufficiency of which are recognised by both of them, agree as follows:

1. PURPOSE

1.1. The purpose of this agreement is the provision by the Association, through the Speaker/Consultant/Expert, of the following services on behalf of the Company:

Identification of Services to be Provided	
Need for the Services to be Hired	

1.2. The Parties acknowledge that the provision of the Services described in this Contract is in no way conditioned to the purchase, use, prescription, incentive or recommendation of any product or service of the Company.

1.3. The Company and the Association should act as independent contracting parties and nothing in this Agreement should be construed as creating any legal relationship of work or subordination between the two Parties.

2. SELECTION CRITERIA

2.1. The Company hires the Association under the terms and conditions set out in this Contract so that the latter can provide, through the Speaker/Consultant/Expert, the services best described in Clause 1;

2.2. The Association declares to be fully responsible for the selection of the qualified Speaker/Consultant/ Expert with the knowledge and experience necessary for the effective provision of the services described in clause 1;

2.3. The Association, through the Speaker/Consultant/Expert, agrees to: (i) provide the Services to the Company, using its best capabilities; and (ii) comply with all applicable professional rules, regulations and standards in

the implementation of the Services, including the Code of Conduct for Relations between the Pharmaceutical Industry and the Patient's Associations, Patient Advocates, Patient Experts, Patients and Caregivers;

3. DURATION

3.1. This contract has a duration of [***** months/years] from the day of its signature, i.e. until [*******], notwithstanding the changes that may be introduced by the parties in written form.

3.2. Both Parties recognise that the extent of the services to be provided is no greater than it is reasonably necessary to meet the needs identified in clause 1.

4. PAYMENT

4.1. In exchange for the development and provision of the Services, the Association receives from the Company the amount of [*** euros], by bank transfer to the stated account which belongs to the Association.

4.2. The two parties recognise that the above-mentioned fees are reasonable and have been set up in accordance with fair market value and that in setting them up, no account has been taken of any past or present business volume and value generated between the Association and the Company.

4.3. The amount set out in clause 4.1. should be transferred to the Association's bank account within [***] days of the date on which the invoice is received by the Company, according to the details below:

Association's Bank Account Data	
Account holder name	
Account holder's address	

Name of the Bank	
IBAN	
Account currency	EURO

5. INDUSTRIAL AND INTELLECTUAL PROPERTY RIGHTS

5.1. The signing of this Agreement should not aim at transferring any intellectual property rights. [OR]

5.1 It is expressly agreed between the Parties that the services described in the first clause of this Agreement constitute commissioned works, the Company being the original and exclusive owner of the intellectual property rights relating to the provision of services by the Association through the above identified Speaker/Consultant/Expert.

5.2. Public use of the logo, name and/or copyrighted materials belonging to the Association and/or the Company in connection with the provision of services which are covered by this Agreement should be subject to prior written consent of both parties, and the application for use must clearly state the specific purpose and manner in which the logo, name and/or copyrighted materials are to be used by the Parties.

6. CONFLICTS OF INTEREST

6.1. Notwithstanding the obligations arising from Decree-Law No. 14/2014, of January 22nd, in the event that any of the representatives of the Association, as well as the "CONSULTANT"/"SPEAKER"/"EXPERT", belongs to a pharmacy committee of a hospital of the National Health System, to a committee with decision-making powers in the assessment of medicinal products or to a scientific society which participates directly or indirectly in decisions concerning the assessment of medicinal products, should declare to that body its relationship with the Company during the

term of this Contract and no later than 12 (twelve) months after its termination and, where appropriate, refrain from taking decisions concerning the Company's products, in accordance with the internal operating rules of the corresponding bodies to which they belong.

6.2. The Patients' Association agrees to publicly declare, further ensuring that its representatives, as well as the CONSULTANT"/"SPEAKER"/"EXPERT agree to publicly declare, that they provide paid services to the Company, whenever they write or speak in public, namely in lectures, congresses, training and awareness-raising courses, among others, on matters under this contract or on matters relating to the Company.

7. TRANSPARENCY

The Association expressly acknowledges that the Company conveys, under the terms and by the means provided for in the applicable legal, regulatory and ethical rules, including the Medicinal Product Statute and the APIFARMA's Code of Conduct for the Relations between the Pharmaceutical Industry and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers, the information relating to this Contract that it is obliged to disclose, namely, the name and contact details of the Association, the purpose of this Agreement and any amounts paid within its scope.

8. DATA PROTECTION

8.1. The collection and processing of personal data of representatives of the Association and of the Speaker/Consultant/Expert provided under this Agreement are necessary for the signing and management of this Agreement and the compliance with legal obligations and are therefore collected under these grounds.

8.2. The Association is responsible for obtaining the consent of its representatives, including the Speaker/Consultant/Expert, whenever it is legally required for the delivery and dissemination of testimonials, lectures, information or clinical data of the latter in order to effectively provide the services. Irrespective of any legal obligation, the Association is also

responsible for obtaining the consent of patients for the use, in the context of the provision of services, of their image and voice, information and clinical data thereof, as well as other data which may enable the identification of such patients.

8.3. The personal data of the representatives of the Association, as well as the personal data of the Speaker/Consultant/Expert may be conveyed by the Company to (i) subcontractors hired by it for the purpose of processing the data, as well as to (ii) entities in which it has an interest in the afore-mentioned scope. In this context, data may be conveyed outside Portugal including to countries outside the European Union whose legislation does not provide adequate security guarantees under Portuguese and European data protection legislation (TO BE ADAPTED TO THE SPECIFIC CASE ACCORDING TO THE PERSONAL DATA'S CONVEYANCE LOCATION). The Company may also convey the personal data of the Association's representatives, as well as the personal data of the Speaker/Consultant/Expert, under the applicable and necessary terms, to the competent authorities and institutions - such as INFARMED, I.P., and APIFARMA - for the purpose of complying with legal, regulatory and/or ethical obligations applicable to the Company.

8.4. The representatives of the Association and the Speaker/Consultant/Expert, as owners of the personal data, may, through the Association, exercise the rights of access, rectification, cancellation, limitation and portability in relation to the personal data included in the mentioned file, as well as oppose the processing, under the terms and with the scope provided for by the applicable laws and, in particular, to revoke the consents provided, by sending a written request to the Company, via e-mail [*******].

8.5. The Association has the right to complain to the national supervisory authority (National Committee for Data Protection - www.cnpd.pt).

9. COMPLIANCE WITH LEGAL, ETHICAL AND REGULATORY STANDARDS

The Association and the Company undertake to implement this Agreement in strict compliance with all applicable laws, regulations and codes of conduct including, but not limited to, the APIFARMA Code of Conduct for Relations between the Pharmaceutical Industry and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers.

10. APPLICABLE LAW AND JURISDICTION

10.1. All matters arising from this Agreement, namely its interpretation, validity, effectiveness or implementation, shall be governed and regulated by Portuguese law, which should apply exclusively.

10.2. Any references to legal provisions or instruments should include subsequent ones which tacitly or expressly will amend, revoke or reinstate them.

11. GENERAL PROVISIONS

11.1. All communication between the Parties concerning this Agreement shall be in writing, by letter, fax or electronic mail, and shall be sent to the addresses stated at the beginning of this Agreement.

11.2. This Agreement represents the full agreement between the Contracting Parties regarding the Support. No other verbal or written agreements have been adopted, which, if any, are set out in this document.

11.3. Any amendments and/or additions to this Agreement should be in writing.

Done and signed at the above-mentioned date and location in two (2) copies, one copy being destined for each of the Parties.

COMPANY X	ASSOCIATION Y
_____	_____

Model C - Services rendered by Patient Advocates to Companies (Articles 6 and 10 of the Code)

a. **Essential requirements which should be included in the written agreement:**
   1. Identification of the parties (Pharmaceutical Industry Company and Patient Advocate);
   2. Need for the Company providing services and identification of the services to be hired;
   3. Payment and payment conditions of the services rendered;
   4. Duration;
   5. Personal Data Protection Clause, as applicable;
   6. Transparency Clause (it should mention the fact that the Pharmaceutical Industry Company will publicly disclose the amounts paid to the Patient Advocate in accordance with the provisions of the law and art. 20);
   7. Obligation of the Patient Advocate to declare that it provides paid services to a Company, whenever they write or speak in public about matters covered by the contract or about matters relating to the Company;
   8. Signature of the Parties involved in the provision of services;
   9. Date of the agreement.

b. **Contractual Model Proposed by APIFARMA**

   This model sets up the essential aspects to be included in a written agreement in accordance with Article 10 (*Provision of Patient Advocates' Services to Companies*). Companies may use this model in its entirety or adapt it to the specific case, as long as they comply with the essential requirements listed above.

   Location, *Date*

PARTIES:

V. **COMPANY X,** with registered office at [******], and its single registration and legal person number [*******], hereby represented by [insert legal representative's name] as Manager, mandated for the purpose, hereinafter referred to as **"COMPANY"**;

VI. **PATIENT ADVOCATE Z,** identified by Citizen's Card No. [*****], living at [*********], hereinafter referred to as **"CONSULTANT"/"SPEAKER"/"EXPERT"**

The **COMPANY** and the **Consultant/Speaker/Expert** shall henceforth be referred to as the "***Party***" when referred to individually and as the "***Parties***" when referred to jointly.

WHEREAS:

I. The Company carries out its activity in the area [*description of the area of activity of the Company*);

II. [TO BE INCLUDED IN CASE THE CONTACT HAS BEEN MADE VIA PATIENTS' ASSOCIATION] The Company, in order to find someone capable and with the knowledge necessary for the provision of the services envisaged in this Contract, contacted the PATIENT'S ASSOCIATION [****] (the "Association"), with the purpose of being informed of which Patient Advocate would be most suitable for the provision of the service in question, given their knowledge and experience in the defence and support of a population of patients living with [*state the disease*].;

III. [INCLUDE IF THE CONTACT HAS BEEN MADE BY THE PATIENTS' ASSOCIATION] The Association, in response to the Company's request, indicates the Patient Advocate [***] as being the appropriate Consultant/Speaker/Expert to provide the services best described in clause 1.1

IV. The Consultant/Speaker/Expert is an individual recognised at national/international level for his knowledge and experience in the defence and support of a population of patients living with the disease [*****].;

V. The Company intends to hire the services of the Consultant/Speaker/Expert,

in order to render the following services defined in clause 1;

The Parties, for the reasons set out above, the content and sufficiency of which are recognised by both of them, agree on the following:

1. PURPOSE

1.1. The purpose of this agreement is for the Consultant to provide the following services on behalf of the Company:

Identification of Services to be Provided	
Need for Services to be Hired	

1.2. The Parties acknowledge that the provision of the Services described in this Contract is in no way conditioned to the purchase, use, prescription, incentive to prescription or recommendation of any product or service of the Company.

1.3. The Company and the Consultant/Speaker/Expert should act as independent contracting parties and nothing in this Contract should be construed as creating any legal relationship of employment or subordination between the two Parties.

2. SELECTION CRITERIA

2.1. The Company hires the Consultant/Speaker/Expert under the terms and conditions set out in this Contract to provide the services best described in Clause 1.

2.2. The Consultant/Speaker/Expert declares that he/she has the knowledge and experience necessary for the effective provision of the services described in clause 1.

2.3. The Consultant/Speaker/Expert agrees to: (i) providing the Services to the Company, to the best of its ability; and (ii) complying with

all applicable professional rules, regulations and standards in the provision of the Services.

2.4 The Company selected the Consultant/Speaker/Expert based on the data and information provided by the Association, which indicated and referenced him for his awareness and experience in defending and supporting a large population of patients living with the disease [******].

3. DURATION

3.1. This contract has a duration of [**** months/years] from the day of its signature, i.e. until [******], notwithstanding any changes which may be made by the parties in writing.

3.2. Both Parties recognise that the extent of the services to be provided is no greater than what is reasonably necessary to meet the needs identified in clause 1.

4. PAYMENT

4.1. In return for the development and provision of the Services, the Consultant/Speaker/Expert receives from the Company the amount of [***] euro by bank transfer to the account mentioned and belonging to the Consultant/Speaker/Expert.

4.2. Both Parties acknowledge that the above Fees are reasonable and have been set at fair market value and that in setting them, no account has been taken of any past or present business volume and value generated between the Consultant/Speaker/Expert and the Company.

4.3. The amount set out in clause 3.1. shall be transferred to the Consultant/Speaker/Expert's bank account within [****] days of the date on which the invoice is received by the Company, according to the details below:

Consultant/Speaker/Expert's Bank Account Details	
Account Holder Name	
Account holder's address	
Name of the Bank	
IBAN	
Account Currency	EURO

5. INDUSTRIAL AND INTELLECTUAL PROPERTY RIGHTS

5.1. The signing of this Agreement should not aim at transferring any intellectual property rights. [OR]

5.1. It is expressly agreed between the Parties that the services described in the first clause of this Agreement constitute commissioned works, whereby the Company is the original and exclusive owner of the intellectual property rights relating to the provision of services by the Association through the Speaker/Consultant/Expert identified above.

5.2. Public use of the name, logo and/or copyrighted materials belonging to the Consultant/Speaker/Expert and/or the Company in connection with the provision of services under this Agreement shall be subject to the written consent of both Parties, and the application for use should clearly state the specific purpose and the way the logo, name and/or copyrighted materials are used by the Parties.

6. CONFLICTS OF INTEREST

6.1. Notwithstanding the obligations arising from Decree-Law 14/2014 of January 22nd, where the Consultant/Speaker/Expert belongs to a pharmacy committee of a hospital of the National Health System, to a committee with decision-making powers in the assessment of medicinal

products, or to a scientific society which participates directly or indirectly in decisions concerning the assessment of medicinal products, should inform that body of its relationship with the Company during the term of this Contract and no later than 12 (twelve) months after its termination and, where appropriate, refrain from taking decisions concerning the Company's products, in accordance with the internal operating rules of the corresponding bodies to which it belongs.

6.2. The Consultant/Speaker/Expert agrees to publicly declare that he/she provides paid services to the Company whenever he/she writes or speaks in public, namely in lectures, congresses, training and awareness-raising courses, among others, on matters covered by this contract or on matters relating to the Company.

7. TRANSPARENCY

The Consultant/Speaker/Expert expressly acknowledges that the Company communicates, under the terms and by the means provided for in the applicable legal, regulatory and ethical rules, including the Medicinal Products Statute and the APIFARMA Code of Conduct for the Relations between the Pharmaceutical Industry and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers, the information relating to this Agreement that it is obliged to disclose, namely, the name and contact details of the Consultant, the purpose of this Agreement and any amounts paid within its scope.

8. DATA PROTECTION

8.1. The collection and processing of personal data of the Consultant/Speaker/Expert and of the Company provided under this Agreement are necessary for the signing and management of this Agreement and the compliance of legal obligations and are therefore collected under these grounds.

8.2. Irrespective of any legal obligation, the Consultant/Speaker/Expert is responsible for obtaining the consent of patients to the use, in the context

of the provision of services, of their image and voice, information and clinical data thereof, as well as other data that may enable those patients to be identified.

8.3. The personal data of the Consultant/Speaker/Expert may be conveyed by the Company to (i) subcontractors contracted by it for the purpose of processing the data, as well as to (ii) entities in which it has an interest within the above-mentioned scope. In this context, data may be conveyed outside Portugal including to countries outside the European Union the legislation of which does not provide adequate security guarantees under Portuguese and European data protection legislation (ADAPT TO THE SPECIFIC CASE ACCORDING TO THE PERSONAL DATA TRANSFER LOCATION). The Company may also convey the personal data of the Consultant/Speaker/Expert, as applicable and necessary to the competent authorities and institutions - such as INFARMED, I.P., and APIFARMA - for the purpose of complying with legal, regulatory and/or ethical obligations applicable to the Company.

8.4. The Consultant/Speaker/Expert, as owner of the personal data, may exercise the rights of access, rectification, cancellation, limitation and portability in respect of the personal data included in the aforementioned file, as well as oppose the processing, under the terms and to the extent provided for by the applicable laws and, in particular, to revoke the consents provided, by sending a written request to the Company by e-mail [******].

8.5. The Consultant/Speaker/Expert has the right to complain to the national supervisory authority (National Committee for Data Protection - www.cnpd.pt).

9. COMPLIANCE WITH LEGAL, ETHICAL AND REGULATORY STANDARDS

The Company and the Consultant/Speaker/Expert undertake to implement this Agreement in strict compliance with all applicable laws, regulations and codes of conduct including, but not limited to, the APIFARMA Code of Conduct for the Relations between

the Pharmaceutical Industry and Patients' Associations, Patient Advocates, Patient Experts, Patients and Caregivers.

10. APPLICABLE LAW AND JURISDICTION

10.1. All matters arising from this Agreement, namely its interpretation, validity, effectiveness or implementation, should be governed and regulated by the Portuguese law, which should apply exclusively.

10.2. Any mention of legal provisions or legal instruments should include any subsequent provisions or instruments that tacitly or expressly amend, revoke or reinstate those provisions or instruments.

11. GENERAL PROVISIONS

11.1. All communication between the Parties concerning this Agreement should be in writing, either by letter, fax or e-mail, and should be sent to the addresses mentioned at the beginning of this Contract.

11.2. This Agreement represents the full agreement between the Contracting Parties regarding the Support. No other verbal or written agreements have been adopted, which, if any, are set out in this document.

11.3. Any amendments and/or additions to this Agreement should be in writing.

Done and signed at the above-mentioned date and location in 2 (two) copies, one copy being destined for each of the Parties.

COMPANY

CONSULTANT/SPEAKER/EXPERT

_____ _____