PHARMABIOTIC RESEARCH INSTITUTE
BYLAWS (VERSION 3.0 – for validation on 20 November 2017)

PREAMBLE

Recent developments of knowledge have shown that understanding of the interactions between the microbiota(s) and its human or animal host could have applications beyond their roles in food and agriculture and that new products emerging from the research relating to the microbiota could be considered as pharmacological agents in their own right, exhibiting a preventive and curative potential of human diseases.

These new pharmaceutical products, emerging from the better understanding of the interaction between the microbiotas and their host, can include any medicinal product containing living, dead or fragments (or a combination thereof), of components of the microbiome (i.e. bacteria, yeasts, phages etc…) with the purpose to prevent or treat human diseases through a pharmacological, microbiological, neurological, immunological or metabolic mode of action, or make a medical diagnosis. In the following document, these products are referred to as "Microbiotic Medicinal Products", or abbreviated "MMP's".

Article 1 – Name of the Association

Therapeutic or prophylactic properties of MMP's should be studied and validated, from research and design all the way to the conditions of production and use, according to suitable pharmaceutical criteria which have yet to be more clearly defined. It is in this light that the **Association** with the name "***Pharmabiotic Research Institute"*** or abbreviated the "PRI" was founded.

Article 2 – Constitution

The PRI is created among the members by the current bylaws and the Association is governed by the French law of July 1st, 1901, and the decree of August 16th, 1901.

Article 3 – General Purpose

The PRI is an Association whose goal is to promote the therapeutic or prophylactic potential of MMP's, including Live Biotherapeutic Products (LBPs).

The PRI will investigate and promote creative ideas from any competent stakeholder that could be useful to adapt or develop pharmaceutical standards for MMP's. This can happen by means of research, conferences, networking, task group activities or direct contacts with competent legal and governmental authorities.

The PRI considers that the microbiome is the future of human medicine and wishes to be at the center of this evolution in Europe. The PRI believes in the strong therapeutic potential of LBPs but in a larger extent to all MMPs.

The PRI is a neutral and financially independent nonprofit association. It is the basis of its neutrality and key for a collaborative approach between actors who might have conflicting interests. In addition, this neutrality is the pre-requisite for a healthy relationship with the competent authorities and the future negotiation relating to regulatory guidelines on MMPs.

At the heart of the PRI is **its collaborative approach** which allows the PRI to more credibly pave the way for regulatory evolutions in Europe. The very essence of the PRI collaborative approach is that stakeholders, as well as competent authorities, may learn from each other and together be able to make a real difference.
In addition, it sheds new light on the decisions which should be made by the actors of the industry, therefore allowing them to better identify the optimal route for their developments.

The PRI is not a consulting firm and the collaborative knowledge produced by the association is to be re-directed towards its members. The PRI does not own any of the intellectual property gathered through the collaborative approach as this information is available to all regulatory members.

To achieve the PRI objectives, the PRI members believe in the following approach:

a: Awareness about the target is necessary to change the current regulatory situation in Europe around MMPs

b: Acceptance of the association as a privileged and competent partner is required in order to reach that goal

b: Value must be delivered to the members

c: Revenue is necessary to support that work

Therefore, the PRI brings Value to its members through different activities such as networking, learning and sharing within task groups, gathering and sharing regulatory information, supporting collaborative research, developing projects by identifying partners, and interacting with competent authorities relating to the evolution of the EU regulatory Framework surrounding MMPs.

However, **the PRI does not provide:**

Paid consultancy services

Marketing activities

Market analysis services

And the PRI is not an observatory of the microbiota and its industry

Article 4 – Specific Goals

The PRI is and acts as a team, remains ambitious and driven, but at the same time also remains humble. The Association states that its objectives will be met by striving for the following goals:

1) Attain state of the art knowledge on pharmaceutical practices;
2) Engage, coordinate and trigger any action in order to kindle the evolution of the European pharmaceutical regulations towards the specific nature of MMPs.

3) Assist members in their development and marketing authorization requests for their MMP's according to European legislation;
4) Form and initiate Task Groups on specific bottleneck topics;
5) Organize public demonstrations, symposiums and seminars by bringing together professionals in the field of microbiota and human health as well as any other entity, person or corporate, which could be advantageous by their own acts or contributions to the realization of the overall goal;
6) Edit, publish, and distribute documents, media, articles within the scope of attaining set goals ;
7) Collect all regulatory knowledge specific to MMP's and distribute this knowledge within the regulatory members of the Association.
8) Facilitate precompetitive research activities by assisting e.g. the finding of suitable research partners and the writing and submission of research projects.

The PRI therefore wishes to be the main representative organization interrogated by the competent authorities regarding the future regulatory framework for MMPs (including LBPs) and to become the number one network for the European microbiome pharmaceutical supply chain, federating fundamental actors from the industry, such as stakeholders involved in the development, investment, production and commercialization of MMPs.

Article 5 – Head Office

The Head Office is now located at 38 AVENUE DE LA REPUBLIQUE, 15000 AURILLAC, FRANCE.
It can be moved to any location within the Auvergne Rhône-Alpes Region by a simple decision of the Board.

Article 6 – Ethics

The PRI shall not engage in price-fixing, anticompetitive agreements, or any other unfair methods of competition that restrain trade and are prohibited under the Sherman Act, Federal Trade Commission Act, and/or other current or future federal and state antitrust laws. Members will also respect the Nagoya Protocol on Access and Benefit-sharing of biological and genetic materials (https://www.cbd.int/abs/about/#objective).

Article 7 – Duration

The Association is formed for an unlimited duration of time.

Article 8 – Membership

a) Categories of Members

The Association proposes different levels of membership.'

1) **'Active Members'** are private corporate entities commercially exploiting or planning to commercially exploit MMPs under whatever form (strain, bulk, or finished product), by any method of distribution, towards all sorts of clients (BtoB or BtoC) in any arena worldwide. Any private corporate entities proposing services to the corporate entities described above may as well be Active Member of the association.

Active Members are also private corporate entities that wish to perform and finance R&D initiatives or create consortium projects in which they employ the expertise and know-how of the PRI.

- 'Active members' are divided into two sub-categories:
    - 'Active **Regulatory Members** are those which are interested in the 'regulatory' activities of the Association;
    - 'Active **Partnering Platform Members**' are those which are interested in R&D activities as well as being put into contact with other actors in the microbiota and human health area;

2) **'Associate Members'** are any academic or public research entities that have developed expertise in the field of research or development of MMP's, as is defined above, and that wish to participate in the realization of the overall goal of the Association.

Corporate entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted to the Association. Associate Members are represented by the researcher having requested membership to the Association or by a person that is officially nominated by the Associate Member's organization.

b) Membership Eligibility

To become a member, the candidate must be confirmed by the Board conforming the process definites in the internal policies and procedures document (annex 1).

The conditions for applying as an eligible active or Associate Member, as well as all associated rights and obligations, are defined in the Association's 'Internal Policies and Procedures' document, annex to this bylaw document.

Every member confirmed by the Board is bound to respect and uphold the Charter of Ethics, annex to this bylaw document, to which it becomes signatory at the start of Association membership.
Corporate entities cannot be considered for admission into the Association as an eligible Active Member or Associated Member without the organization having first received authorization from the Board. The Board decides with or without cause, and without any possibility of appeal. The membership dues, following the authorization of the Board, confirm the membership of the organization.

Private entities having capital venture, consulting, or technology transfer activities cannot have access to the regulatory membership as they cannot act as intermediate organizations to disseminate regulatory collaborative knowledge built by the Association's regulatory members to third parties which are not PRI members.

In order to safeguard this principle at all times, every Regulatory Member will have to sign a non-disclosure agreement about the dissemination of the Association's regulatory collaborative knowledge generated by the regulatory members. This non-disclosure document, annex to this bylaw document, will have to be signed by all new and existing Regulatory Members at the time of acceptance of the current bylaws (Version 3.0).

A separate non-disclosure agreement will have to be signed between the PRI and the representative of an active Regulatory Member when she/he is also personally involved in remunerated activities, managing activities, or is a share owner of one or more corporate entities which are not listed as Regulatory Member of the PRI. When the representative of a Regulatory Member assigns a replacement member in case of illness or for any other reason, the temporary representative will be prone by the same conditions of confidentiality as the official representative. It is the responsibility of the Active Member to inform its temporary representative on the conditions subscribed by the representative of a Regulatory Member concerned.

c) Loss of Membership Eligibility

Membership of the Association can be lost by Situations that change the company conditions to the extent that they are no longer in agreement with the initial conditions of membership acceptance by the Board. Such situations can be, but are in no way limited to:

1) The dissolution of the corporate entity (notably by mergers, acquisitions,…), , or the declaration of a bankruptcy recovery plan or court-mandated liquidation for such corporate entity.
2) Non-payment of membership dues, despite two notifications of late-payment.
3) The violation of the bylaws, the internal policies and procedures, the Charter of Ethics, or, for Regulatory Members, the violation of the non-disclosure agreement.

Dismissal is pronounced by the Board, after a hearing session in which the Member failed to explain the alleged facts or propose an acceptable remediation. The procedure of dismissal of a member is described on the annex 2 “Charter of Ethics”, article “Disciplinary Actions”.

Dismissal is notified by the President of the Association by registered mail.

d) Rights and duties of the Members

All Active and Associate Members shall be entitled to display the Association’s logo in their advertising and/or promotional material but not on commercial products, and shall, unless explicitly requested otherwise, automatically be listed on the Association’s website.

Article 9 – Finances

The resources of the Association are composed of:

1) Membership dues calculated as lined out in the Internal Policies and Procedures document;
2) European, State (France), regional, departmental, and local grants
3) Research funding obtained for traveling, coordination-, management- or dissemination activities;
4) Private donations and donations from state-approved organizations;
5) Income resulting from property sold, or from services rendered by the Association;
6) Revenue from property and assets of any nature owned by the Association;
7) Donations and bequests that the Association may be authorized to accept on the grounds of the nature of its purpose;
8) All resources authorized by law, jurisprudence, and any responses received from the ministries.

Article 10 – The Board and Executive Director

a) Composition

The Board is composed of minimum 2 and maximum 25 members, elected by the ordinary General Assembly, for a term of not more than 2 years, drawn from both active and associate members, by a show of hands or by secret ballot (if at least one of the members requests the latter).

Associate Members are limited to a maximum of 5 Board members at any given time.

Corporate entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted to the Association.

One half of the Board is to be reelected every year by the General Assembly.

Exiting Board members are eligible for reelection, with no limitation of the number of reelections.

In the case of one or more vacant Board seats, such seats are to be filled during the next General Assembly.
An Association Member can propose to replace his or her Board member. Upon acceptance of the candidate by the Board, the term of the new Board Member will end at the same time as the term of the replaced Board member would normally have expired.

The services of a Board Member cease by resignation, loss of membership, three consecutive unexcused absences from the Board meetings. A Board Member is dismissed by the General Assembly, which can take place *ad nutum* and by a simple meeting. Dismissal is notified by the President of the Association by registered mail.

The terms of the Board members are served without financial compensation.

b) Powers of the Board Members

Board Members are provided the power for managing, directing, and administrating the Association, except for those activities explicitly reserved to the General Assembly. The Board is presided by the President of the Association, or in his/her absence, by one of the Vice-Presidents. Board activities include, but are not limited to:

1) nominating and appointing the PRI Executive Director and other PRI staff members as well as and defining their powers, salaries and other privileges, financial or not;
2) defining the vision and the general orientation of the Association in choosing the actions to be carried out;
3) creating dedicated *ad hoc* Task Groups whenever this is deemed useful for the Association.
4) deciding on the main course of action concerning communication and public relations, in the goal of raising awareness of the activities of the Association towards health authorities, as well as the scientific and academic communities;.

5) ratifying and controlling the budget and expense evolution, ensuring the financing of current and future projects ;
6) determining the level of annual membership dues;
7) acceptation of new Members as well as the exclusion of existing Members;
8) deciding sanctions against a member in case of violation of the bylaws, the ethical principles and rules of the Charter, the internal policies and procedures and the non disclosure agreement;
9) deciding on the acquisition or transfer of movable property and furnishings, the ordering of repair- and renovation arrangements, and buying or selling of deeds, securities, etc.;
10) leasing or acquiring the building necessary for the day to day functioning of the Association, conferring any lease or mortgage of the buildings owned by the Association, carrying out the sale or the exchange of said buildings, and applying for loans and offers, including the establishment of all guarantees and assurances;
11) submitting the annual balance sheets;
12) dismissing the Executive Director and other staff members;
13) ensuring that the duties of the Executive Director are carried out;
14) appointing a financial auditor, both a titular and a substitute, when legally necessary;
15) approving and modifying the Association's Internal Policies and Procedures, the Charter of Ethics and the non-disclosure agreement;
16) authorizing the acts and commitments which exceed the scope of the President's explicit powers;
17) ratifying the dismissal of members;

c) The Executive Director

The Executive Director is nominated by the Board and reports back to the Board for actions carried out by the Association.
The Executive Director is responsible for all day to day activities of the Association and should ensure the execution of the program of activities voted by the Board and the general assembly as well as the execution of the duties of the other PRI staff members.
The Executive Director is the first level of contact for the Association. Depending on the required action he/she will decide on the necessity of the involvement of the Board and/or the President, bearing in mind their respective roles as defined in this bylaws document.
Any delegation of power from the President of the association or from the Board to the Executive Director will be detailed in a Document signed by the President and the Executive Director.

d) Operating Rules for the Board and Executive Director

The Board meets at least twice a year, on the initiative of and by the summoning of the President, or in the case that he/she is unavailable by one of the Vice-Presidents. The Board may meet by way of web conferencing.

The Board can also meet on the initiative of one third of the Board membership, on the request of the Executive Director, followed by the summoning of the president.

Summonses are carried out by mail or email, and, except for emergency meetings, must reach the Board Members at least 8 days before the date chosen for the meeting.

The agenda is established by the President based on the proposal made by the Executive Director. When the Board meets on the request of one third of its members or at the request of the Executive Director, the agenda should explicitly specify the reason for such meetings.

The Board of Directors may only legitimately deliberate if at least half of the membership is present or represented. If this quorum is not reached, the session is adjourned and the president shall summon a new Board meeting with the same agenda at a later date. At said date, the Board may then deliberate, no matter the number of Members present or represented.

Decisions are made by a simple majority vote. In the case of a tie, the President's vote acts as a tie-breaker.

Any Board member unable to attend may decide to be represented by any other Board member of his/her choice; to this effect a specific voting proxy power document should be signed by both parties. The number of such powers held by a single member shall not exceed two. Any Board member not present may also remit their voting powers to the Head Office.

The Executive Director is invited to participate in all Board meetings in an advisory role. He/she does not participate in the vote of any decisions. When absent for substantiated reasons, his/hier role is taken over by the President or by a PRI staff member nominated for that role by the President. He/she can be asked by the President to leave the Board meeting.

The Board may invite any expert to assist in its deliberations.

Minutes are taken of every Board meeting by the Secretary or one of the PRI staff members. The minutes are made without omission or erasure, and signed by both the President and a Board member; they are re-transcribed in chronological order, within the records of deliberations of the Association, given a classification entry and initialed by the President.

e) Emergency Board meeting

When deemed necessary by the President, an extra emergency Board meeting can be called. Summons in this case are carried out by telephone during which a common meeting time is agreed. The date is confirmed by mail or email and will contain the details of the agenda for this emergency meeting. The quorum of half of the Board members must be reached for such emergency board meetings to take place.

Article 11 – Executive Committee

The Executive Committee meetings of the Association are presided over by the President.
The Executive Committee of the Association is composed of the President, one to three Vice-Presidents, a Secretary and Treasurer, flanked by a Deputy Secretary and Deputy Treasurer, when nominated.

Members of the Executive Committee are elected by the Board and are chosen from Members of the Board among the candidates who have been proposed within a month before

the general assembly meeting takes place. Voting takes place by a show of hands; except if a secret ballot is requested by at least one of the members. The members of the Executive Committee are elected for a term of two years. Exiting members are eligible for reelection. The elections take place during the Board committee that takes place just after the general assembly.

The services of a member of the Executive Committee cease by resignation, loss of membership eligibility in the Association, dismissal by the Board of Directors, which can take place *ad nutum* and by a simple incident meeting, and by the dissolution of the Association.

The Executive Director is invited to participate in all Executive committee meetings in a advisory role. He doesn't participate to the vote of any decisions.. When absent for substantiated reasons, her/his role is taken over by the President or by a PRI staff member nominated for that role by the President. He can be asked by the president to leave the Executive committee.

Article 12 – President

a) Position

The President concurrently holds the positions of President of the Board and of the Association. Board Members representing Regulatory or Partnering Platform Members can be candidates for the Presidency of the Association only if they are also involved in academic activities. The Board will be responsible for validating that candidates meet with this condition.

b) Powers

The President governs the daily management of the Association. He/she acts in the name of and on the behalf of the Association, under the supervision of the Executive Committee and the Board.
In particular, the President:

1) represents the Association in all of the matters of civilian life, and possesses all powers to such an effect;

2) is representing the Association in court, as a plaintiff or defendant; he/she may only be replaced by a mandated proxy acting by virtue of a special power of attorney;

3) may, under his/her own initiative, file any and all legal actions in court, for the defense of the interests of the Association, consent to any settlements, and mount any appeal;

4) summons the Board and the General Assemblies, sets their agendas, and presides their meetings;

5) is empowered to open and operate, in any bank or financial institution, any monetary accounts or savings;

6) carries out the decisions ratified by the Board;

7) signs any contract of purchase or sale and, more generally, all documents and contracts necessary for the execution of the decisions of the Board and the General Assemblies;

8) has control over all expenditures;

9) presents an annual progress report to the General Assembly;

10) may delegate, in writing, his powers and signature to a member of the Board or to the Executive Director; he/she may at any moment put an end to such delegated powers; the President must keep the Board up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

Any documents and engagements beyond the scope of the powers defined above will have to be authorized beforehand by the Board.

Article 13 – Vice-President(s)

The Vice-President(s) are elected by the Board members among the candidates proposed within one month before the General Assembly Meeting takes place.

In the event that the President cannot fulfill his duties, he/she is replaced by the Vice-President most senior in age.

The Vice-President(s) has the responsibility of assisting the President in the course of his/her duties. The Vice-President(s) may act in the President's stead, but always under the President's direction. The Vice-President(s) may receive specific empowerments, temporary or permanent, defined by the President.

The Vice-President(s) may delegate, in writing, his/her powers and signature to a member of the Board or the Executive Director. The Vice-President(s) must keep the Board up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

Article 14 – Secretary and Deputy Secretary

The Secretary is elected by the Board members among the candidates who have been proposed within a month before the General Assembly Meeting takes place.

The Secretary watches over the material, administrative, financial, and legal operations of the Association.
The Secretary takes the minutes of the meetings of the Executive Committee, Board of Directors, and General Assemblies, as specified in Article 10d. The Secretary compiles the records of the Association.

The secretary conducts all legal notifications to the local representatives of government (*préfecture*), and to the official government register (*Journal Officiel*), with respect to the regulatory or legal provisions.

The Secretary may delegate, in writing, a Deputy Secretary or, in absence thereof, a member of the PRI staff to execute the above tasks on his/her behalf. The Secretary must keep the Executive Director up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

The Secretary may act on the President's authority.

Article 15 – Treasurer and Deputy Treasurer

The Treasurer and Deputy Treasurer are elected by the Board of Directors among the candidates proposed within a month before the General Assembly Meeting takes place.

The Treasurer records the annual accounting of the Association.

The Treasurer is responsible for the annual collection of membership dues.

The Treasurer compiles a financial report, which he/she presents along with the annual accounting of the Association to the annual General Assembly. The Treasurer is empowered to open and operate, in any bank or financial institution, any monetary accounts or savings.
The Treasurer presents the annual budgets and sees to their implementation.

The treasurer may sign any contract of purchase or sale and, more generally, all documents and contracts necessary for the execution of the decisions of the Board and the General Assembly.
In partnership with the Executive Director the Treasurer keeps track of all records of requests for grants and subsidies.
The Treasurer may complete or initiate the payment of expenses and the depositing of moneys paid.

The Treasurer may delegate, in writing, to a Deputy Treasurer or, in absence thereof, a member of the PRI staff to execute the above tasks on his/her behalf. The Treasurer must keep the president and the Executive Director up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

Article 16 – General Assemblies

a) Common Provisions

All members of the Association, once they have paid their membership dues, have access to the General Assemblies and may participate in voting.

Each member holds One vote.

1) Corporate entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted beforehand to the Association.
2) The General Assemblies are summoned by the President by mail or email at least one month in advance. The summons contains the agenda set by the President. General Assemblies may also be summoned on the initiative of one third of the members. This one third may request the listing of desired questions or points of discussion on the agenda.
3) The members sign a presence sheet when entering the General Assembly Meeting. This may be a physical paper or an electronic registration in case of a web-based conference meeting.
4) At the beginning of each General Assembly Meeting, a chairing committee is composed of at least the President, the Secretary and the Executive Director.
5) The President presides over the General Assemblies, outlines the points on the agenda, and guides the debates (Article 12b-4). The most senior Vice-President stands in for the President in the event that he/she cannot fulfill their duties (Article 13).
6) The General Assembly may only rule on the points of the agenda, with the exception of the dismissal of members of the Board (Article 10a).
7) The General Assembly Meetings are either 'Ordinary', or 'Extraordinary': their decisions, which have been passed according to the law, are mandatory for all concerned.
8) Any Association Member unable to attend a General Assembly Meeting may be represented by another Association Member holding a special power to this effect.
   The number of such powers held by a single member shall not exceed two.
   Any Board Member not present may remit their voting power to the Executive Director. Such powers are then to be distributed by the President amongst the Board Members by preference and the members of the General Assembly in second rang, respecting the aforementioned limitations (Article 10d). .
9) Absentee voting is forbidden.
10) The Executive Director as well as any other relevant PRI staff member may be invited to participate in the General Assembly Meeting in an advisory role. In addition, when deemed necessary, any Member of any Task Group can be invited to participate in the General Assembly Meeting in an advisory role.
11) The General Assembly may invite any expert to assist on its deliberations.
12) Votes are counted by a show of hands or are recorded by a certified electronic or web-based system..
13) Minutes are taken by the Secretary (Article 14), registering the proceedings and resolutions passed by the General Assembly during the General Assembly Meetings. The minutes are made without omission or erasure and signed by both the President and the Secretary of the session; they are re-transcribed in chronological order, within the records of deliberations of the Association, and given a classification entry and initialed by the President.

b) Ordinary General Assemblies

1) Powers

The Ordinary General Assembly convenes at least once a year, within the six months following the end of the fiscal year. When necessary additional Meetings can be organized

on the initiative of the President, or on the initiative of at least one third of the Association Members.

The Ordinary General Assembly hears the progress report, the financial report, and if it should occur, the report of a financial auditor.

The Ordinary General Assembly signs off on the balance sheet of the closing fiscal year, votes on the provisional budget and acknowledges that the Board has properly managed the Association's finances.

The Ordinary General Assembly decides on agreements referred to in article L.612-5* in the French code of commerce, which are to be submitted to the General Assembly by the President, or, if these exists within the Association, by the financial auditor(s).

The Ordinary General Assembly elects and dismisses the members of the Board.

The Ordinary General Assembly authorizes the Board to sign all official documents, to bring to a close any commitment, and to incur duties which go beyond the scope of their statutory powers.

The Ordinary General Assembly decides the specific themes and subject of each task group

The Ordinary General Assembly deliberates on all points of the agenda, especially those which do not explicitly come under the sphere of another body of the Association.

2) Quorum and Majority

The Ordinary General Assembly may only legitimately deliberate if one third of its Members are present or represented. If the quorum is not reached by the first summons, the Ordinary General Assembly is to be re-summoned, but no less than 8 days after and with the same agenda. At this time, the Assembly may legitimately deliberate, whatever the number of Members present or represented may be. Members may participate by way of web conferencing.

Decisions are made by a simple majority of votes.

c) Extraordinary General Assemblies

1) Powers

It is within the authority of the Extraordinary General Assembly to go forward with changes in Bylaws, the dissolution of the Association and the dispersal of its assets, and the merging or transformation of the Association. In a general manner, it is within the authority of the Extraordinary General Assembly to make any decisions which may change the nature of its existence or its main purpose.

The Extraordinary General Assembly is summoned each time as is necessary, by the initiative of the President or by the initiative of at least a third of its members.

2) Quorum and Majority

The Extraordinary General Assembly may only legitimately deliberate if one third of its members are present or represented. If the quorum is not reached by the first summons, the Extraordinary General Assembly is to be re-summoned, but no less than 15 days after and with the same agenda; at this time, the Assembly may legitimately deliberate, whatever the number of members present or represented may be.

The decisions are made by a majority of two third of the members present or represented.

Article 17 – Fiscal Year

The fiscal year begins October 1st and ends September 30th.

Article 18– Accountancy – Accounts and Annual Balance Sheets

The Association records the annual accounting, according to current standards of accounting and bookkeeping.

The annual balance sheets are made available for every member, along with the annual progress report, the financial report, and, whenever available, the financial auditor's report, during the 15 days preceding the date of the Ordinary General Assembly summons.

Article 19 – Financial Auditors

If the legal conditions are met, the Board appoints a head financial auditor, as well as a deputy financial auditor, registered on the list of auditors of the *Compagnie Régionale*.

The financial auditor carries out his/her duties according to the norms and rules of his/her profession. The financial auditor composes and presents, each year, a report rendering an account of his/her work and certifying the regularity and sincerity of the accounts in the presence of the ordinary General Assembly that is to rule on the balance sheet of the closing fiscal year.

Article 20 – Dissolution

In case of dissolution, the extraordinary General Assembly designates one or many liquidators who are in charge of the liquidation operations. At the closure of the liquidation operations, the Extraordinary General Assembly pronounces the dispersal of the net assets conforming to the French law of July 1st, 1901 and of the French decree of August 16th, 1901.

Article 20 – Internal Policies and Procedures (ANNEX 1)

The internal policies and procedures, in Annex 1 of this document, is updated by the Board and specifies and compliments, such as needed, the statutory measures related to the operations of the Association. Accession to the Bylaws is an implied accession to the internal policies and procedures. Any changes must be communicated to all members of the Association.

Article 21 – Ethics Charter (ANNEX 2)

The Ethics Charter, in Annex 2 of this document, is updated by the Board and specifies the ethical dos and donts of the Association. Accession to the Bylaws is an implied accession to the Ethics Charter. Any changes must be communicated to all members of the Association.

Article 22 – Non-disclosure document (ANNEX 3)

The non-disclosure formulations, in Annex 3 of this document, are updated by the Board and specify the secrecy conditions to be respected by the Regulatory Members when they join the Association. Accession to the Bylaws is an implied accession to the conditions specified in this non-disclosure document. Any changes must be communicated to all Regulatory Members of the Association.

Name:

Company/ Corporate entity:

Please write the phrase " *read and approved*", the Date, and your Signature:

ANNEX 1
PHARMABIOTIC RESEARCH INSTITUTE (PRI)
Internal Policies and Procedures

Role and Objectives of the Association:

The PRI is built upon a common vision:

- Propose and develop the standards of evaluation of **Microbiotic Medicinal Products - MMPs** (any medicinal product containing living, dead or fragments (or a combination thereof), of components of the microbiome (i.e. bacteria, yeasts, phages etc…) with the purpose to prevent or treat human diseases through a pharmacological, microbiological, neurological, immunological or metabolic mode of action, or make a medical diagnosis).Actively participate in the promotion of MMPs potential applications among health authorities and industry leaders for their development and production.
- Promote the microbiota and health industry at the European level with the objective of obtaining an adapted and pharmaceutical regulatory framework for these products.

I: Organization of the Association:

- **The members:**

The Association recognizes two types of members described in the bylaws of the association:

Corporate entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted to the Association.

Private entities having capital venture, consulting, or technology transfer activities cannot become regulatory members as they cannot act as intermediate organizations to disseminate regulatory collaborative knowledge built by the Association's regulatory members to third parties which are not PRI members.

The acquisition and the loss of membership as well as the rights and duties of members, having been enumerated in the bylaws, will not be restated in this document.

The process of acquiring membership is as follows:
By the request of a company wishing to become a member, the PRI is to transmit a membership contract which will require all information about the corporate entity, its executive, the physical person named to represent the corporate entity within the PRI, and the table of membership fees.
This document is to be filled out by the future member and sent back by mail or email to the headquarters of the Association.
Once this document has been received by the Association, an invoice of the membership fees will then be sent to the new member.

For regulatory members, the invoice is accompanied with a Non-Disclosure Agreement (NDA) to be signed by the person duly authorized to engage the corporate entity / laboratory in such agreement as well as another NDA to be signed by the official representative named in the membership contract under his own name.
Once the membership fees have been paid, and the NDAs signed sent back to the PRI, the membership is then confirmed by the Board. The representative of the new member is to receive one copy of the bylaws including the annexes I (Internal policies and procedures), II (Ethics Charter) and III (NDA) for its records.

A corporate entity may decide to replace or withdraw its representative at any time and without any justification. To this effect, the entity simply must send by regular mail a letter, or email, to the Executive Director of the Association, which will then confirm reception of the document.
This withdraw will take effect once the member has received confirmation of reception.

If this representative was a member of the Board or the Executive Committee, the vacant seat will be filled during the next General Assembly meeting (as enumerated in the bylaws).

The Board of Directors, by a majority vote, may ask a member to replace its representative at any moment and without justification if this representative, as long as this representative is not a member of the Board or the Executive Committee.

The conditions of loss of membership, having been enumerated in the bylaws, are not the subject of this document.

In the event that membership status is lost, the membership fee will not be reimbursed.

Except for special authorization by the PRI, any active or associate members have an obligation of confidentiality and non-distribution of the information and reports produced by the Association. The same goes for the scientific fore-sighting which the task groups will build upon, and for internal PRI publications.

All PRI members (partnering platform, regulatory, associates) may make request to the Business Development Manager for their networking needs and partner search.

II: Organization and Operations of the Task Groups:

- **Composition of the Task Groups:**

The Task Groups are composed of representatives of any interested member.

The representatives of each member have the right to participate in as many task groups, or activities carried out by the association, as they would like. Each member may choose to be represented by different individuals, employees of the member-company, in each task group or activity so as to offer specific expertise concerning the different topics addressed.

All task group participants are invited to participate in an advisory role to the General Assembly meeting.

Members may choose to nominate the representative of their choice depending on the different themes treated by the task group.
Members must inform the Executive Director of a PRI staff member in charge of organizing meetings, of their representatives to such meetings. In every situation, only the employees of the member-company may represent their companies within the task groups.
For Associate members, multiple representatives may participate in the task groups considering the specificity and expertise of different laboratories which may or may not belong to the same public corporate entity.
Concerning the experts and opinion leaders belonging to a public corporate entity-member or non-member of the Association, it is the responsibility of Executive Director, under request of the task group members, to establish a list of recognized experts for each task group or theme treated, to contact these experts and opinion leaders, and to invite them in the name of the PRI to participate in the task group meetings. All of this is for the purpose of preserving the independence of these experts within their fields.

Task group members have the opportunity to decide on a chairman elected from the task group members. If no members propose his candidacy for the chairman position, the Executive Director, or the PRI staff member who was nominated by the Executive Director fur such purpose, will coordinate the task group work on his own.

In the event that the candidates are too numerous for a single task group, the participants are chosen by the Executive Director, according to their recognized and complimentary expertise for the group's subject.
He/she is required to respect a certain balance between, on the one hand, participants of Associate and Active members, and on the other, fundamental research and pharmaceutical development expertise.

The different task groups, corresponding to different themes, will be formed following the discussion on the activity program proposed by the Executive Director at the opportunity of the PRI annual Ordinary General Assembly, and will be approved by the Board.

- **Mission of the Task Groups:**

The mission of the task groups is to, if needed, work on the development of adapted standards of evaluation for MMPs as well as on the communication of the state of the art of the science relating to the microbiota and human health..
The subjects treated by the task groups may touch upon any step of the process of marketing a MMP as medicine (from the more scientific aspects all the way to regulatory affairs) as well as any subject of reflection relating to the evolutions of the strategy of the association or its communication.

For each subject treated, and proposed to the members during the general assembly, the task group is responsible for:

- A global survey of all research projects, current validation methods, and the research teams and their associated stakeholders who are working on the subject in question. For this purpose, the group will be supported by the PRI staff members.
- The drafting of guidelines in step with the work of the task group.
- The drafting of position papers in step with the work of the task group.
- The drafting of any communication document or support relating to the strategy of the association or its communication.

- **Task Group Operations:**

The specific themes of the different task groups will are proposed by the Executive Director during the annual Ordinary General Assembly.

The frequency of the meetings and the overall organization of the meetings will be decided by the members of the respective task groups at the opportunity of the first task group meeting.

For their participation, the physical persons belonging to an Associate member may be reimbursed for their expenses, related to their activities as a participant of a task group, according to a table set by the Board .

The remuneration or reimbursement of expenses of physical persons (opinion leader) invited to participate in task group meetings, by demand of its participants, will be discussed on a case by case basis and must be approved by the Executive Director according to the provisional budget approved by the Board for the task group activities

The PRI in support of the task groups puts at their disposal the following:

- Practical organization of meetings.
- Logistical financing of meetings.
- The proofreading of the work written by the task groups in English.
- The fees relating to the publication of any position paper

- **Confidentiality:**

Except for special authorization by the PRI, any participant of any task group has an obligation of confidentiality and non-distribution of the information and reports produced by the task-groups, as well as on any document provided by the PRI along the discussions of such task group.

ANNEX II

Charter of Ethics of the Pharmabiotic Research Institute (PRI)

The Pharmabiotic Research Institute wished to equip itself with a Charter of Ethics so that the relationships of the members, those belonging to the academic worlds of research and education and those belonging to a company, can be developed from a base of common rules of behavior; It is in essence the expression of an alliance and solidarity which is indispensable to the legitimacy of the Pharmabiotic Research Institute - PRI in any future relationship with French and European Health Authorities.

To this end, the Pharmabiotic Research Institute is inspired by the ethical code of the members of the Council of Science and Technology of Quebec (*le Conseil de la science et de la technologie du Québec*), as well as the Charter of Ethics of the French National Research Agency (*Agence Nationale de la Récherche)*, and the Charter of Ethics of the *Médicen* cluster (*Pôle de compétitivité Médicen*).

General Purpose and Scope of Application

1: This Charter states the ethical rules and principles of the members of the Pharmabiotic Research Institute, whether they are active members, associate members or paid staff.

2: This Charter's goal is to establish proper rules of behavior among the partners of the PRI, in particular with respect to competition/antitrust law. This must be the case, for example, within the task groups, the theme-specific commissions, the Executive Committee, and the Board of Directors, as well as any future contact with potential investors.

3: Those employed or otherwise in the service of the PRI fulfill their duties for the benefit of the Association. In particular, they must be aware of the existence of the multiplicity of organizations, national agencies and member-companies and act in an impartial and equitable manner towards them all.

General Principles

The guiding principles enumerated in this Charter may not, on their own, describe all acts that are to be avoided, nor may they explain all activities that are favorable or ideal. It is beholden upon any member implicated in any way with an activity of the PRI to act honestly and with good judgment and to respect all applicable laws, basing his behavior on the notion that his decisions are made in the interest of the PRI; this goes for the principle of confidentiality as well, which applies to any information of which he is privy to, or to the opinions expressed during meetings of the membership.

The following sections of this document principally address the proper behavior to adhere to in situations of any conflict of interest, more specifically any situation where a member of the PRI may find himself incapable of following the rules found within.

A conflict of interest is meant as any and all situations where an individual is brought to pass judgment or take part in a decision-making process from which his professional activities could directly or indirectly benefit.

This applies even to a member simply having an understanding or awareness of information from which the member, or the enterprise that the member belongs to, could potentially profit from by either using them or distributing them.

This notion of conflict of interest can apply to, according to the situation, a group of individuals, an organization, an association or a company.
This is treated in detail in the following situations:

- The assessment of a project in which members, their close coworkers, and employees of their laboratories or their companies are implicated.
- The assessment of a project which, economically-speaking, is competitive to one in which members, their close coworkers, and employees of their laboratories or their companies are implicated.
- The decision or the use of information which could be advantageous to a member-company.
- The decision or the use of information which could prove to be disadvantageous to a competitive project in which members, their close coworkers, and employees of their laboratories or their companies are implicated.

In summation, participation in the PRI must not be used to acquire, use or distribute information, in any way contrary to ethical behavior, in order to develop one's own business or commercial dealings, now or in the future.

Duties and Obligations:

Rigor and Integrity:

Members are to carry out their duties to the best of their ability and knowledge with rigor, timeliness, diligence and integrity.

Discretion:

Members are held to the utmost level of confidentiality with regards to the facts and information which they have become aware of in the course of their duties and which have been declared as "confidential" by the authors of these facts or the distributers of this information. Overall, members of the PRI must demonstrate reserve and discretion with regards to any information received which does not become open for public consumption.

Neutrality and Respect:

All members are bound to conduct themselves with the utmost respect towards other members, and to abstain from provoking or participating in any conflict of a personal, ethical, political or religious nature. Members are bound to neither provoke nor participate in any discussion which does not primarily pertain to established data or facts or the analysis thereof.

Prudence:

Members must demonstrate prudence and take all necessary precautions before communicating information not intended for public consumption concerning the PRI.

Conflicts of Interest:

- Members must avoid putting themselves into any actual, potential, or seeming conflictive situations of a financial or moral nature, between their personal interests and those of the PRI and its members.
- Any member of the association, as part of any meeting of the Association, who has been called to become familiar with a project, under the penalty of law, must state any direct or indirect interest which could potentially put him/her in a situation leading to or causing a conflict of interest. This declaration must be made during the meeting.
- Any member of the Association, who has been called to become familiar with a project, must as a precondition and under penalty of law declare in writing to the Board of Directors of the PRI any direct or indirect interests which could potentially put him/her in a situation leading to or causing a conflict of interest. Such a member must be absent from the debates and discussions concerning said project.
- When needed, the Board of Directors takes every measure to anticipate any risk of collusion or any decision that could be considered as favoritism. The Board of Directors announces these in writing. Notably, this could lead to the temporary replacement of those susceptible who are concerned with such risks.
- Any expert or consultant outside of the PRI who is hired to work on a project must sign a declaration attesting to their having no conflict of interest and to a confidentiality agreement.
- Any member of the Association who contributes to a project may not, under penalty of law, embark upon a competitive activity to said project (which by definition would place a member in an economic conflict of interest with another partner of the project). This obligation is to last for the entire life of the project and extend to a full two years after the project has been completed.
- Members may not use unpublished confidential information, which is not for public consumption and solely obtained in the execution of their duties, to their profit or to the profit of a third-party, without at least the expressed authorization of the President of the PRI.
- In the case of questions or doubt concerning a possible conflict of interest, it is for those concerned to contact the Executive Director and the Board of Directors in order to obtain an adequate ruling on the subject.
- In order to avoid all conflicts of interest, no contract or any form of financial contribution may be accepted by the direction of the PRI.
- Members may not solicit or accept a favor or inappropriate advantage for themselves or on behalf of third-parties.

Behavior after members' terms expire:

It is forbidden for elected members, applying to the two years following their term of service, to divulge confidential information obtained in the exercise of their former duties or to use it for their profit, or for the profit of a third-party, information not intended for public consumption which was obtained in the scope of their duties.

Means of Application

The President of the PRI is responsible for implementing and applying this Charter. The President must be assured that each member is aware of this Charter and that its ethical principles and rules are respected by everyone.

Any member of the Association, who represents the organization or company on which he/she depends in situations of deliberation or who participates in an operational capacity of the Association, is obliged to respect this Charter.

All members of the PRI must declare in writing to the Board of Directors any potential conflict of interest at the time of membership and any conflict of interest which may occur afterwards.

Disciplinary Actions:

In the case of a violation of the ethical principles and rules of this Charter, and in case of violation of the bylaws, internal policies and procedures and the non-disclosure agreement the Board of Directors shall take action toward the accused member.

Members who are accused of those violations, may be provisionally relieved of their duties on behalf of the Executive Director, who then informs the Board of Directors, which then allows them to take appropriate action in an emergency situation or in case of an alleged serious infraction.

The Board of Directors announces to the member accused of the violation as well as the penalty which could be imposed and informs him that he may, within seven days, provide the Board his observations on the matter and, if he asks, to be heard on the subject.

In conclusion, if a member has violated the ethical principles and rules set out by this Charter, the Board of Directors is to sanction him.

A sanction is either imposed by way of reprimand or by dismissal from the Association. This sanction must be with just cause and put into writing. Any dismissal must be made public on the Association website.

ANNEX III

NON DISCLOSURE AGREEMENT

This Agreement is made and entered into on **.....[date]** (hereinafter referred to as "the Effective Date") by and between:

The PHARMABIOTIC RESEARCH INSTITUTE Association (loi 1901), having its principle place of business at **38 AVENUE DE LA REPUBLIQUE, 15000 AURILLAC, FRANCE**, represented by **Magali CORDAILLAT-SIMMONS**, who is duly authorized for the purpose hereof

Hereinafter referred to as « The Association»,

AND :

…….. [company Name], …….. [company type], having its principle place of business at **…… [location],** registered at RCS of **…….[country]** under the number **……[number]**, represented by **……[name]**, who is duly authorized for the purpose hereof.

Or : …….. [Name], …….. [position], …….. [company].

Hereinafter referred to as « The Member»,

The Association and the Member will be hereafter referred to separately as "**the Party**" and jointly as "**the Parties**".

WITNESSETH:

1) Members of the PRI are of Three types:
   - The Associate Members who are from the academic world and only benefit in the networking activities as well as the collaborative R&D project engineering and do not have access to the regulatory knowledge and regulatory work of the Association.
   - The Partnering Platform Members who are private entities from the microbiota and human health industry and only benefit in the networking activities as well as the collaborative R&D project engineering and do not have access to the regulatory knowledge and regulatory work of the Association.
   - The Regulatory Members who are private entities or from the academic world and have access to all services provided by the association including the networking activities, the collaborative R&D project engineering as well as the regulatory work and the collaborative knowledge produced by the Association.

2) The PRI and its Regulatory Members are involved in the Association's discussions relating to the PRI work on the regulatory strategy to adopt in order to develop and register probiotics as medicinal products, i.e. Live Biotherapeutic Products (*hereinafter referred to as "the Discussions"*).
3) The information produced through the PRI work is unique as it is obtained through a collaborative approach. Therefore such information is owned by the PRI but not by its Regulatory Members. The PRI exclusively allows its Regulatory Members to use this information in order to develop their own products according to the best regulatory standards and for their own use only but does not allow the dissemination of the information. For the sake of clarity, Associate members as well as Partnering Platform members do not have access to such information and certain private entities are not eligible for the regulatory membership, i.e, companies involved in technology transfer, capital venture, and other companies involved in consulting which could use this confidential information for parties which are not Regulatory Members of the PRI.

4) As a consequence, in the framework of the Discussions and all Projects carried out by the Association, including its collaborative work, the Parties acknowledge that the Association as well as the Regulatory Members may disclose some highly confidential information. Therefore the Regulatory Members of the PRI, as well as the persons representing such member organization, are responsible for the non dissemination of such highly confidential information and the Parties agree to conclude this present agreement in order to protect this confidential information

NOW, THEREFORE, in consideration of the above premises and the following covenants contained herein, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

For the purpose of this Agreement the following terms shall have the meaning ascribed to them, provided that the singular included the plural.

1.1 « **Agreement** » : means this present agreement, including its preamble, together with the Annex hereto.;

1.2 « **Effective Date** » : means the **……[date]**, date of the first discussions between the Parties ;

1.3 « **Confidential Information** » : means all information, data and documents disclosed by the Disclosing Party of any nature whatsoever, such as commercial, scientific, technical, legal, economic, regulatory and financial, and any form whatsoever, such as oral, written or electronic, including but not limited to the know-how, ideas, patentable or not, the dosage, formulation, regulatory dossiers, technology, technic, innovation, rules on calculation, clients, compensation, products, processes, raw materials , colors, projects, activities, concepts, specifications, designs, methods, components, strategies, inventions, combinations, results and resources, products and processes, other than those expressly designated by the Disclosing Party as non-confidential information, disclosed directly or indirectly by the Disclosing Party to the Receiving Party during the term of the Agreement or prior to signing it, or which the Receiving Party may be aware, in any form whatsoever, during the same period

1.4 « **The Disclosing Party** » : means the Party which discloses Confidential Information;

1.5 « **The Receiving Party** » : means the Party which receives Confidential Information;

ARTICLE 2. Obligations of the Parties

The Receiving Party undertakes indefinitely, on its behalf and in the name and on behalf of its employees and collaborators:

a) to maintain strict confidentiality of the Confidential Information;

b) not to operate or use, directly or indirectly, in the world, in any form whatsoever, any Confidential Information other than for the purpose of the Discussions and the Project, unless a written and prior agreement of the Disclosing Party;

c) to disclose the Confidential Information to its employees and collaborators who absolutely need to know their content for the purpose of the Discussions and Project, provided cumulatively that (i) the Receiving Party shall ensure and be liable for the compliance by such employees and collaborators of the commitments stipulated in this Agreement, and (ii) such employees and collaborators sign a non disclosure agreement incorporating substantially the same terms of this Agreement and (iii) the Receiving Party takes a regularly updated list of the names of persons having access to the Confidential Information and shall provide to the Disclosing Party this list upon the Disclosing Party's first request, in a format readable by the latter.

d) not to copy, distribute, communicate, transfer or transcribe the Confidential Information by any means whatsoever, except in cases where this is necessary for the execution of the Agreement and is expressly authorized by the Disclosing Party

e) not to, directly or indirectly, or ask or allow a third party to copy, reproduce, alter, adapt, operate reverse engineering (trying to imitate or reproduce in any way manufacturing processes and products) integrate in all creation, work, product or service, in any manner whatsoever, all or part of the Confidential Information.

f) to return, upon the Disclosing Party's first request, all written copies or other permanent forms containing Confidential Information and/or destroy all notes, reports or documents on any medium whatsoever issued by the Receiving Party, if they contain references to Confidential Information. The Disclosing Party shall be entitled to require a certificate of destruction of such documents.

ARTICLE 3. Communication of Confidential Information

3.1. The Disclosing Party shall only provide to the Receiving Party Confidential Information that it deems necessary to enable the Receiving Party to implement the Project.

3.2. The Disclosing Party remains the sole owner of its Confidential Information. No elements mentioned hereby shall be interpreted as conferring to the Receiving Party any transfer, license or rights regarding any intellectual property rights or Confidential Information, which remain the ownership of the Disclosing Party. The Receiving Party undertakes not to claim such rights and/ or initiate any action or proceeding, in order to, directly or indirectly, file any patent, patent application and/or obtain any right relating to the Confidential Information.

ARTICLE 4. Exclusions

Shall not be considered as Confidential Information, the ones which the Receiving Party may prove that:

(i) was publicly known and made generally available in the public domain prior to the time of disclosure by the Disclosing Party; or becomes publicly known and made generally available after disclosure by the Disclosing Party through no action or inaction of the Receiving Party;

(ii) is independently developed by the Receiving Party without use of or reference to the Disclosing Party's Confidential Information

(iii) is obtained by the Receiving Party from a third party without a breach of such third party's obligations of confidentiality;

(iv) the disclosure is required by law, provided that the Receiving Party has notified this obligation of disclosure to the Disclosing Party as soon as possible

ARTICLE 5. LIABILITY - WARRANTY

5.1. The Parties acknowledge and agree that any Confidential Information are made available "as is". The Parties do not express any representation and/or guarantee, explicitly or impliedly, regarding the Confidential Information disclosed, with respect to its validity or its accuracy, whatever the Information may be, representation or guarantee according to which the use of the Confidential Information is free from any infringement of third party rights or any other compensation claimed by a third party.

5.2. The Receiving Party acknowledges and agrees that the Confidential Information may be related to developing products, services or processes or doomed to be developed. The Disclosing Party shall not guarantee to the Receiving Party that the aforementioned products, services or processes will be put into trade; the Confidential Information being disclosed only as a rough guide and likely to be modified by the Parties.

5.3. The Parties acknowledge hereby that any violation or threatened violation of this Agreement shall may cause an important injury, which will need to be fully repaired.

In addition, The Receiving Party shall indemnify the Disclosing Party for all costs resulting from such implementation, including but not limited to, reasonable attorneys' fees and the entire prejudice if it exceeds the amount of the above mentioned indemnity.

5.4. The Parties acknowledge hereby that any violation or threatened violation of this Agreement shall may cause irreparable injury to the Disclosing Party, for which damages do not constitute a sufficient compensation, and as such, thereof, the Disclosing Party shall be able to claim an enforceable compensation, in addition to any other remedy that the Disclosing Party may use, before courts or in equity. If the Disclosing Party manages to exercise its rights pursuant to this Agreement, the Receiving Party, in addition to all due damages, shall have to repay to the Disclosing Party every costs resulting from such an enforcement, including, but not limited to, reasonable attorney's fees. The Receiving Party acknowledges its liability for all harmful consequences resulting from the use of the Confidential Information that may be done by one of its executives, employees, representatives or consultants in breach of this Agreement.

ARTICLE 6. TERM - TERMINATION

6.1. This Agreement comes into effect as of its Effective Date and will remain in force :

(i) During all the legal protection to current and future French and international laws in force, including all extension which may be added to this duration concerning technical processes, know-how, trade secrets and more generally any information carried out for the performance of this Agreement likely to be protected by intellectual property rights.

(ii) As long as the Confidential Information shall not make generally available in the public domain available through no action or inaction of the Receiving Party for all other Confidential Information and at least for ten (10) years subsequent to its expiry or termination.

6.2. At the end of the Project, the Receiving Party is not authorized to use the Confidential Information

ARTICLE 7. GOVERNING LAW AND JURISDICTION

7.1 This Agreement shall be governed by and interpreted in accordance with French law at the exclusion to any international convention

7.2 In the event of a dispute, controversy or claim (hereinafter referred to as "Dispute"), arising out or in connection with this Agreement, including any question regarding its existence, validity or termination, such Dispute shall be exclusively and finally determined and settled by the Commercial Court of Clermont-Ferrand – France

ARTICLE 8. MISCELLANEAOUS

8.1 If one of the Parties is subject to a sale, merger or other form of reorganization involving a third party, the terms of the Agreement will bind the legal successor of the foresaid Party in the same terms as its predecessor. However, the Party subject to such restructuring shall immediately and without delay notify the other Party.

Subject to the foregoing, no Party may assign all or part of its rights or obligations under this Agreement without the prior and written consent of the other Party.

8.2 The conclusion, existence and execution of this Agreement remain confidential and shall not be disclosed to third party without the priori and written agreement of the other Party.

8.3 This Agreement may not be modified and/or amended, nor any obligation waived, except by a writing signed by both parties hereto.

8.4 All covenants contained herein are severable. In the event any such covenant is found to be invalid, unlawful or unenforceable to any extent by any competent court, this Agreement shall be interpreted as if such invalid unlawful or unenforceable agreements or covenants were not contained within this Agreement

8.5 The failure of either Party to enforce any provision of this Agreement in a particular instance, , shall not constitute a waiver of such Party's right to enforce such provision unless such right has been expressly waived in writing.

8.6 Any notice required or permitted to be given under this Agreement shall be given in writing and shall be addressed to the principle place of business of the Parties, as indicated in the first page. Such notice may be given by registered letter with acknowledgment of receipt and shall be effective a the date of dispatch. Any modification of the address of the Parties shall be notified to the other Party.

The Parties hereby have duly made the present Agreement in two original duplicates, on behalf of each Party at the respective dates stated below.

The Member	**The Association**
Company: ……..	**Pharmabiotic Research Institute**
Represented by	**Represented by**
Name: ……	**Name: Magali Cordaillat-Simmons**
Date: ……..	**Date: ……..**
Signature:	**Signature**