

Phages for Human Applications Group Europe

P.H.A.G.E. / STATUTES

Undersigned:

Debarbieux Laurent Marie (Fr.)
De Vos Daniel Maria (B.)
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Vanechoutte Mario Gilbert Karel Cornelius (B.)
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declare by this act the founding of a non-profit Association (hereafter called VZW), in accordance with the Belgian Law of 27th June 1921, modified by the Law of 2nd May 2002 that is assigning corporate rights to non-profit Associations, international non-profit Associations and to foundations. The Association's Statutes are defined as follows:

TITLE I: NAME – SEAT – AIM – DURATION

ARTICLE 1

The Association is named: Phages for Human Applications Group Europe, abbreviated as P.H.A.G.E.

ARTICLE 2

The seat of the Association is located in Queen Astrid Military Hospital, C Dis / Site NOH, Blok C, 1st Floor, Office 1.391, Bruynstraat 1, 1120 Brussels, Belgium and is a part of the judicial district of Brussels, Belgium.

This seat can only be moved by the General Assembly, provided that the rules as required for a modification of the Statutes and as described in those Statutes, are respected.

ARTICLE 3

The P.H.A.G.E. Association aims to develop a specific regulatory framework for the use of bacteriophages.

Phages are Nucleic Acid containing virus-like particles that are completely harmless to humans. They are however extremely selective and efficient bacterial killers. They are the only mechanisms capable of controlling the natural bacterial populations. They co-evolve with the bacteria and this in the strict Darwinian sense of the word. When resistance against a phage ensues, mutations in the phage genome can undo this resistance in the matter of days to weeks. As such, phages are potentially important and sustainable disinfecting (phage prophylaxis) and antibiotic (phage therapy) agents.

P.H.A.G.E. consists of Members that share an interest in the development of phage knowledge and phage application (prophylactic as well as therapeutic). Its Members are originating from EU Member states or from abroad, but its work is restricted to the EU. The work area comprises activities on the European policy level. Members are typically scientists, medical doctors, and specialists in the fields of health economics, legal-, regulatory- or quality control-matters.

The Goals of P.H.A.G.E. are:

1. Build consensus, coordination and guidance, within the EU, regarding
 - a. the definition of a specific legal framework for phage therapy and phage prophylaxis;
 - b. the definition of the application fields of phage therapy and phage prophylaxis;
 - c. the creation of a broad technical and scientific base for phage applications, with an emphasis on production standards (GMP protocols).
2. Offer streamlined information to the authorities and their partners by:
 - a. performing a financial analysis (cost-benefit) on the European and national (for some countries) level;
 - b. helping standardize fundamental research, pre-clinical experiments and clinical trials in order to obtain timely, reliable and relevant results (safety, efficacy, niche applications,..).
3. Act as one of the interlocutors with the regulatory authorities for the specific categorization of phage therapy, and this on the European as well as on the Member state level.
4. Promote the conception and realization of fully controlled clinical trials under the supervision of leading Ethical Committees, in order to obtain reliable and relevant (pre-)clinical data, and this through:
 - a. the exchange of individual phages or phage repertoires;
 - b. the exchange of study protocols;
 - c. the enlargement of studies into (international) multi-centric studies;

- d. assuring that all clinical trials obtain the approval from leading Ethical Committees.
5. Promote and facilitate the gathering and the spread of objective phage knowledge through:
 - a. the exchange of well-characterized phages and phage-related data between partners;
 - b. the coordination and reinforcement of transnational research projects;
 - c. helping generate and augment funding for phage therapy or phage-related fundamental research;
 - d. the organization of coordination meetings, scientific reunions and study days.
6. Facilitate the communication between scientists, clinicians, the public and the industry.

The Association may start any action that promotes these Goals. Accordingly, some business activities are possible, but only in addition to the activities outlined above and only as far as the generated profits are spent on the Goals the Association was created for.

The initial Goals and/or ideology at the founding of the VZW cannot be changed. This clause is fixed.

Changing the initial Goals and/or ideology of the VZW ends the legal existence of the VZW. This clause is fixed.

ARTICLE 4

The Association is established indefinite in time, but can be dissolved at any time.

TITLE II: MEMBERS

ARTICLE 5

The number of Members is unlimited, but must be at least 6. Undersigned founders are the first Effective Members.

The founders are lifetime Members of the General Assembly (unless they voluntarily resign themselves). They cannot be excluded from the General Assembly, unless in case they appear to be mentally insane, according to the Law of 26th June 1990 concerning the protection of insane persons, unless in case a suspicion of absence was noticed by the court of first instance or a declaration of absence was pronounced (according to the definition in the civil code), or unless in case they are declared incompetent (according to the definition in the civil code) and in a more general way if there is any judicial sentence. This clause can't be changed.

The Association can contain Effective and Joined Members. A full Membership, including the right to vote in the General Assembly, is exclusively reserved to the

Effective Members. Effective Members are those who, at the founding, undersigned the articles of the Association and those whose name is registered in the Members' list, kept at the seat of the Association. The legal terms are only applicable to Effective Members. Joined Members are only affiliated to benefit of the activities of the VZW. They do not have the right to vote in the General Assembly. The rights and the obligations of Joined Members are stipulated in a domestic code ("house rules").

ARTICLE 6

Any natural or legal person recognized as such by the General Assembly can join the Association and this by recommendation of the Board. The request for acceptance of a candidate new Member must be submitted in writing to the President of the Board. In these Statutes, the designation 'Member' is explicitly reserved to the Effective Members.

ARTICLE 7

The Board Members can, under specific conditions to be established by themselves, admit also other persons, such as honorary Members, protecting Members, supporting or advising Members, to the Association. They are considered as Joined Members. Their rights and obligations are stipulated in a domestic code.

ARTICLE 8

The maximum Membership is 250 EUR.

ARTICLE 9

Any Member can, at any time, leave the Association. The resignation has to be addressed to the Board in an official writing.

ARTICLE 10

Leaving or excluded Members, and their successors can not participate in the Association's capital. Therefore they cannot claim a refund or compensation for the paid contributions or donations.

TITLE III: THE BOARD

ARTICLE 11

The Association is lead by a Board consisting of at least 3 persons, who are or are not Members of the Association. If the General Assembly only counts 3 Members, the Board will consist only of 2 Members. In any case, the number of Board Members must be less than the number of Members of the General Assembly.

ARTICLE 12: Duration of the mandates of the Board Members

The Board Members are assigned for a period of 3 years, but are re-electable. Interim Board Members are only assigned for the remaining time of the mandate.

Contrary to the general rule, the first Board, created at the formation, is elected for a period of one year.

ARTICLE 13: Way of assignment and financial compensation of the Board Members

The Board Members are assigned by the General Assembly with a normal majority, regardless of the number of present and/or represented Members. Board Members carry out their mandate without financial compensation. The acts concerning the appointment of the Board Members must be deposited at the court of commerce and must be published, within 30 days after deposition, in the appendices of the National Law Gazette (“Belgisch Staatsblad”).

ARTICLE 14: Termination of a mandate and dismissal of Board Members

The Board Member’s mandate comes to an end through dismissal by the General Assembly, through own resignation, through expiration of the mandate (in such case), or through decease.

Dismissal by the General Assembly is decided by normal majority of the present and/or represented Members. However it must be put explicitly on the agenda of the General Assembly.

A Board Member, who is resigning voluntarily, must announce this in an official writing addressed to the Board. The resignation starts immediately, unless the amount of Board Members does not reach the minimum stipulated in the Statutes. If this minimum is not reached, the Board has to organize, within two months, a General Assembly that has to find replacement for the resigning Board Member and let this also know to the resigning Board Member in writing.

The documents concerning the termination of a mandate and the appointment of new Board Members must be submitted at the court of commerce and must be published, within 30 days after submission, in the appendices of the National Law Gazette (“Belgisch Staatsblad”).

ARTICLE 15: Empowerment of Board Members

The Board runs and represents the Association. The Board is competent in all matters except for those reserved by Law to the General Assembly. It represents the VZW in all court procedures and decides to go or not to go to court.

The Board appoints and dismisses Staff Members and decides about their financial compensation.

The Board exercises its empowerment as a College.

The Board can only take a valid decision if a majority of Board Members is present. The decisions are made by normal majority of votes. When suspension of votes, the vote of the President or his substitute is decisive.

The voting is secret.

ARTICLE 16

The Board is convened by the President or by two Board Members.

The meetings of the Board are lead by the President. If he cannot be present, the meeting is chaired by a substitute appointed by the President.

ARTICLE 17

Minutes of every meeting are written. They are signed by the President and the Secretary and kept in a specific register. The documents that must be submitted and all other acts are signed for validation by the President and the Secretary. In absence of those Board Members, two other Board Members can sign the documents for validation.

ARTICLE 18

The Board issues all domestic rules that it considers necessary or useful.

The Board can, if it considers this to be useful, appoint an Administrator or Director, who is charged with daily business. He will be responsible for current affairs and the daily mail, he will sign valid related to the postal services, the public and private banks and all other institutions.

ARTICLE 19

Board Members operating on behalf of the Association should not provide any proof of decision nor form of authorization.

ARTICLE 20: Persons authorized to represent the Association, according to art. 13, 4° lid, W.VZW

The Board can, on its own responsibility, delegate its empowerments to one of the Board Members or another person, Member of the Association or not. The Board can elect, from its Board Members, a President, a Secretary, a Treasurer and any other function that appears necessary for the good functioning of the Association.

The Board decides, by normal majority, about their assignment. The decision is Effective when a majority of Board Members is present.

Termination of the mandate of those authorized persons occurs:

- a) voluntarily, by the authorized person himself, by handing in a letter of resignation to the Board.
- b) dismissal by the Board, with normal majority of votes, when the majority of the Board Members are present. The decision of the Board must be announced in an official writing, within 7 calendar days, to the person involved.

The documents concerning the termination of a mandate or the assignment of the persons authorized to represent the Association, must be deposited at the court of

commerce and must be published, within 30 days after deposition, in the appendices of the National Law Gazette (“Belgisch Staatsblad”).

The authorized persons perform their duty separately or in collaboration, In justice and in all other cases, the Association is legally represented by the President, the Secretary or the Treasurer. They may act on their own.

ARTICLE 21: Persons in charge of the daily management of the Association, according to art. 13bis, 1° lid, W.VZW.

The Board can appoint a daily management.

The Board decides, by normal majority, about the assignment of the Daily Board. The decision is Effective when a majority of Board Members is present.

Termination of the mandate of the Daily Board occurs:

- a) voluntarily, by a Member of the Daily Board himself, handing in a letter of resignation to the Board.
- b) through dismissal by the Board. The dismissal is Effective when a majority of the Board Members is present. The decision of the Board must be announced in an official writing, within 7 calendar days, to the person involved.

The documents concerning the termination of a mandate or the assignment of Members of the daily management must be deposited at the court of commerce and must be published, within 30 days after deposition, in the appendices of the National Law Gazette (“Belgisch Staatsblad”).

Decisions of the Daily Board, functioning as a board, are always taken as a College.

TITLE IV: GENERAL ASSEMBLY

ARTICLE 22

The General Assembly consists of Effective Members, and is chaired by the President of the Board, or by a substitute appointed by the President.

A Member may let himself be represented by another Member at the General Assembly. A Member however is only able to represent one other Member. Every Member possesses only one vote at the General Assembly.

Voting is secret.

ARTICLE 23

The General Assembly is competent in the following matters:

- adaptation of Statutes
- assignment and dismissal of Board Members
- assignment and dismissal of Commissioners and fixing their financial compensation in case a financial compensation is attributed
- lay down responsibilities of Board Members and Commissioners
- approval of the budget and of the account

- voluntary cancellation of the Association
- assignment and exclusion of a joined Member of the Association
- turning the Association into a company with a social goal
- all matters in which the Statutes do require it

ARTICLE 24

The General Assembly is convened by the Board or by the President every time the Goals of the Association require this.

The assembly must be convened at least once a year to validate the accounts of the past year and the budget for the next year.

ARTICLE 25

The General Assembly is held within a period of 6 months after the closure date of the fiscal year.

ARTICLE 26

The Board is also obliged to call together the General Assembly when 1/5th of the Effective Members ask it in an official writing to the Board, containing the agenda items to be treated. In this case the Board must convene the General Assembly within 30 days, mentioning the requested topics on the agenda.

ARTICLE 27

To be considered as valid, the appeal of the General Assembly must be signed by the President or by 2 Board Members. All Effective Members are convened by normal letter, by official letter or by electronic mail at least 8 days before the assembly is held.

ARTICLE 28

The invitation letter to convene the General Assembly, mentioning place, day and the time at which the assembly is held, contains the agenda fixed by the Board. Each topic that has been submitted in writing by 1/20th. of the Effective Members, shall also be put on the agenda. This item has to be signed by 1/20th. of the Members and shall be submitted to the President of the Board at least 2 working days before the meeting. Items that are not on the agenda never can be discussed.

ARTICLE 29

In normal situations, decisions are made by normal majority of the present or represented votes. When suspension of voting occurs, the vote of the President, or the person leading the assembly at that moment, is decisive.

ARTICLE 30: Modification of the Statutes

A modification of the Statutes is only considered if the modification is described in detail in the agenda and if 2/3rd of the Effective Members are present or represented. If such a number is not reached, a second assembly can be convened, as defined in the Statutes. At this second assembly a valid decision can be taken, regardless the number of present Members. This second assembly cannot be held within a period of 15 calendar days following the first assembly. For each modification of Statutes, a 2/3rd majority is needed, also at the second General Assembly.

ARTICLE 31

For each modification of the Statutes, the changes and the fully coordinated Statutes must, after modification, be deposited at the court of commerce. The modification must be announced within 30 days after deposition in the appendices of the National Law Gazette (“Belgisch Staatsblad”).

ARTICLE 32

A majority of 2/3rd of the votes is needed to exclude a Member. An exclusion of a Member must also be mentioned on the agenda. The concerned Member has to be invited so he/she can defend him/herself.

ARTICLE 33

Minutes are taken at every meeting. They are signed by the President and the Secretary and are kept in a special register. This register can be consulted by the Members or any concerned party, at the seat of the Association. Extracts are signed for validation by the President and the Secretary or by two Board Members. In absence of these persons, it can be signed by two Members of the General Assembly.

TITLE V: ACCOUNTS AND BUDGETS

ARTICLE 34

The fiscal year of the Association runs from the first of January till the thirty-first of December.

The Board closes the accounts of the last fiscal year and prepares the budget of the next fiscal year. Both are submitted for approval to the General Assembly that is held within a period of six months following the closing date of the fiscal year.

TITLE VI: DISSOLUTION AND LIQUIDATION

ARTICLE 35

Except cases of judicial dissolution or of dissolution by right, only the General Assembly can decide to dissolve the Association, provided that 2/3rd of the Members are present or represented at the General Assembly and on the one hand 4/5th of the founding Members, who are still having their seat in the General Assembly, agree with a dissolution by own free will, and on the other hand 4/5th of the total number of Members of the General Assembly agrees with a dissolution by own free will. The

proposal of dissolution by free will must be put explicitly on the agenda of the General Assembly.

In case 2/3rd of the Members are not present or represented on this General Assembly, a second General Assembly must be convened, so that it can discuss in a legitimate way, regardless the number of present Members and provided that a double 4/5th majority is found, agreeing to dissolve the Association by free will.

In case of dissolution by free will, the General Assembly, or in default of it, the court, appoints one or more liquidators. She also defines their empowerment of these liquidators and the conditions of liquidation.

After discharge, remaining assets will be donated to another non-profit Association. The decision of dissolution, and the appointment and the termination of the mandates of the liquidators must be deposited at the court of commerce. Within 30 days after deposition, this dissolution decision, and the appointment and the termination of mandate of the liquidators, must be published in the appendices of the National Law Gazette (“Belgisch Staatsblad”).

ARTICLE 36

Anything that is not covered nor regulated by the Statutes will keep falling under the scope of the Law of 27th June 1921, modified by the Law of 2nd May 2002.

Accepted and signed by the Founding Members of P.H.A.G.E. during the First General Assemble (Founding Meeting) taken place on 03/03/2009

Founding Members / First General Assemble:

Debarbieux Laurent Marie (Fr.)
De Vos Daniel Maria (B.)
Dublanchet Alain (Fr.)
Forterre Patrick (Fr.)
Lavigne Rob Bert Jan (B.)
Patey Olivier Nicolas Henri (Fr.)
Pirnay Jean-Paul Raymond (B.)
Vaneechoutte Mario Gilbert Karel Cornelius (B.)
Verbeken Gilbert Livien (B.)
Zizi Martin Dominique (B.)

First Board Members (Elected for 1 Year During the First General Assemble):

Dublanchet Alain (Fr.)
Patey Olivier Nicolas Henri (Fr.)
Pirnay Jean-Paul Raymond (B.)

Vaneechoutte Mario Gilbert Karel Cornelius (B.)
Verbeken Gilbert Livien (B.)
Zizi Martin Dominique (B.)

First Authorized Persons (Elected for 1 Year):

Zizi Martin Dominique (Fr.): President
Pirnay Jean-Paul (B.): Secretary
Verbeken Gilbert (B): Treasurer

Other Functions (Appointed at Founding Meeting / 1 Year):

Dublanchet Alain (Fr.) : Vice-President & Webmaster
Patey Olivier (Fr.): Scientific Coordinator / Clinical
Vaneechoutte Mario: Scientific Coordinator / Fundamental

Dutch / French Statutes of P.H.A.G.E., published in the Belgian National Gazette (“Belgisch Staatsblad”) are provided on request.