

STATUTES OF SMA EUROPE E.V.

PREAMBLE

The association SMA Europe e.V. was founded in 2007 by 7 non-profit national patient organisations in the field of SMA / neuromuscular diseases. Over the years it has grown to 13 full members. These are:

- AFM (France)
- Asociația SMA Care (Romania)
- CSMA (Ukraine)
- DGM (Germany)
- Famiglie SMA (Italy)
- Fundacja SMA (Poland)
- FundAME (Spain)
- NSMA (Sweden)
- VSN/ PBS (The Netherlands)
- SMA Family Foundation Russia
- SMA Schweiz (Switzerland)
- SMA UK
- FSMA, Iceland

Furthermore, the following associated members have been added to this list until this day:

- Stop SMA, North-Macedonia
- SMÁci, Czech Republik
- SMA Serbia
- Muskelsvindfonden, Denmark

Furthermore, the following patient organisations currently have observer status with limited rights and will have to decide on full or associate membership in the coming months:

- SMA Finland
- SMA Belgium

In 2007, when the association was founded, no drug for the treatment of SMA was approved or in clinical trial stage. This has changed since then, which has led to an expansion and shift in the focus of the association's work and the patients' perspective. The association is now no longer only predominantly in demand in the area of support of research and science, but must also increasingly seek and maintain contact with industry, the EMA and the national drug approval authorities and the health authorities in order to achieve the greatest possible consideration of patient interests there as well. The new therapies and the increasing knowledge on the disease are also changing the "standards of care" that must be made accessible to all patients. The structure of the association has to be adapted due to the new tasks and the increased number of members. This necessitates an extensive amendment to the statutes of 2007.

For reasons of linguistic simplification, the reference to both genders is omitted in the statutes. All terms used in this statute are to be understood gender-neutral and non-discriminatory.

§1 Name, registered office and financial year

- (1) The name of the association is SMA Europe e.V.
- (2) The registered office is in Freiburg im Breisgau, Germany.
- (3) The financial year is the calendar year.

§2 Purpose, tasks and goals

- (1) The purpose of the association is to promote the health and healthcare of people living with spinal muscular atrophy (patients, family and caregivers) and to promote science and research in all areas of life affected by SMA.
- (2) To achieve this purpose, the main tasks of SMA Europe include:
 - Representing the interests of people with SMA among all stakeholders in European health policy;
 - Advancing common action at the European level in the research and development of medicines and new therapies (e.g. conducting patient surveys, participating in patient and scientific advisory boards of the pharmaceutical industry and regulatory authorities, organising or attending scientific congresses);
 - Pushing ahead with joint action to achieve Europe-wide access to the best possible treatments and care for all patients with SMA (e.g. conducting patient surveys, developing and publishing patient and doctor information on treatment and care standards);
 - Sensitising the general public, health professionals, academia and industry to SMA;
 - Supporting measures to introduce early and accurate diagnostic tools for SMA in all member countries (e.g. lobbying for the inclusion of SMA in the newborn screening programme of member countries);
 - Expanding and promoting cooperation with and among national affiliates;
 - Collaborating with other worldwide organisations, groups and institutions with similar or complementary goals.

This list is not meant to be exhaustive. The association can take on additional tasks if they fulfil and/or preserve its purpose.

§3 Common good

- (1) The association exclusively and directly works for the common good as a non-profit organisation within the meaning of the section entitled "Tax-privileged Purposes" of the German Abgabenordnung (AO).
- (2) The association's activities are charitable. It does not primarily pursue its own economic interests.

- (3) The association's funds may only be used for the purposes indicated herein.
- (4) Members shall not receive grants from association funds.
- (5) No person may receive pay or reimbursement for expenses that are disproportionate or not related to the purposes indicated herein.

§4 Remuneration and expense allowances for association activities

- (1) Members of the board, delegates of the general meeting, and third parties who work for the association are entitled to compensation for their necessary and reasonable expenses verified with audit-proof receipts.
- (2) The general assembly may grant members of the board compensation for the time and labour spent on the purposes of the association up to the volunteer allowance stipulated in §3 No. 26 a of the German Income Tax Act (EStG), provided the financial position of the association makes this possible and it does not endanger the purpose of the association.
- (3) If the budgetary situation so permits, the board may appoint full or part-time employees to manage the association's office.
- (4) The board is authorised to outsource tasks required of the association (e.g. external accounting, preparation of documents for association register and tax authorities, organisation of congresses, undertaking of surveys) for a reasonable fee or expense allowance, if the budgetary situation of the association allows it.
- (5) Further details on reimbursable expenses and remunerations may be stipulated by the general assembly in supplementary rules of procedure which would then be subordinate to these articles.

§5 Association funds, audits

- (1) The association obtains the funds for its operations from the following:
 - a. Grants from national or international organisations, industry
 - b. Cash and in-kind donations
 - c. Subsidies
 - d. Income from collections and promotions
 - e. Income from the association's assets
 - f. Other contribution
 - g. Membership fees
- (2) The books of the association must be audited annually by at least one auditor. The auditor is nominated by the board and elected by the general assembly for a term of two years. He/she may belong neither to the board nor a committee appointed by the board and may

not be an employee of the association. The auditor shall prepare a report and submit it to the board. A report on the annual audit is to be given to the general meeting, but this does not necessarily have to be made in person.

§6 Members

- (1) The association has both full members and associate members with limited rights.
- (2) Members of the association are national organisations for spinal muscular atrophy (SMA) in Europe and national organisations for neuromuscular diseases in Europe that share a common commitment to European cooperation in the field of SMA. In exceptional cases, non-European SMA organisations may also become members.
- (3) Full members have all membership rights and duties. Associate members have limited rights.

§7 Rights and duties of members, acquisition and termination of membership

- (1) Full members have the right to speak at the general assembly and enjoy one vote per member organisation.
- (2) Full members have passive and active voting rights.
- (3) Associate members have the right to participate and speak in the general assembly, but have no vote and no active and passive voting rights.
- (4) The application for a regular or associated membership is to be addressed in writing to the board, which will make a preliminary ruling on this application in writing within one month of receipt. If rejected, the applicant may file a one-time appeal in writing within 4 weeks after receipt of the corresponding notice from the board. The next ordinary general meeting will then decide whether to approve the new member's application with a simple majority of votes.
- (5) Applications accepted by the board must be submitted to the next general assembly which will then decide by a simple majority of votes whether to accept the applicant as a full or associate member. Applicants have the right to participate and to speak at this meeting on the agenda item "Decision on membership applications".
- (6) Associate members may apply for full membership at the next general meeting after their admission as an associate member. A written request must be submitted to the chair at least 4 weeks before said meeting. The general assembly decides on the application for the conversion from associate to full membership by a simple majority of the general meeting.
- (7) A candidate may request observer status for one year before applying for full or associate membership. During this time, the candidate may attend meetings of the association

without speaking or voting rights. It may also be active in working groups, but shall not take any leadership roles therein. Observers have no active or passive right to vote. A membership fee is not charged to observers. The application for admission as observer shall be decided in accordance with paragraphs 4 and 5 above. Before the end of the observation year, the candidate must apply for membership in accordance with paragraphs 4 and 5 if they wish to continue to participate in the association. If it fails to do so, the observation year ends and no further participation in meetings of the association and working groups will be permitted.

(8) Membership is terminated through:

- a. Dissolution of the member organisation
- b. Resignation with written notice at least 2 months prior to the end of the financial year
- c. Exclusion by the board for good cause. A member may be excluded if it violates these statutes, acts in conflict with the interests of the association, or has repeatedly violated the interests of the association. A clear written statement of the grounds for exclusion must be given to the member. The exclusion is made by the board and requires a simple majority. Before the decision is taken, the member shall be given the opportunity to respond in writing within 14 days. The member may appeal the board's decision to the next ordinary general meeting within one month; the general meeting then takes the final decision with a simple majority of the vote. Until such time, the excluded member's rights are suspended.

(9) With the termination of membership, all rights and responsibilities as a member are forfeited.

(10) The general meeting sets the membership fees for full and associate members.

(11) In addition to the provisions of these articles, the general meeting may pass rules covering membership and contributions which are subordinate to these articles.

§8 Bodies of the association

The bodies of the association are

- the general assembly
- the board

§9 General assembly

(1) Each member organisation will designate according to its own rules no more than 3 persons (2 delegates and one substitute) to represent it in SMA Europe business. It would be desirable for the representatives to be SMA patients themselves or their relatives or at least be staff of a member organisation that focuses on SMA. Delegates should normally be appointed for the long term, but for at least for a minimum term of 2 years. New

delegates may be named outside of this cycle for good cause. Otherwise, it is up to each member organisation to determine how its delegates are selected at the national level.

- (2) At the general assembly, full members with voting rights participate with a maximum of 2 delegates each and associate members participate with 1 delegate.
- (3) Regardless of how many delegates attend the meeting, each member organisation entitled to a vote only has the one vote.
- (4) A full member may assign its voting right to another member of SMA Europe. Notice of this assignment must be provided in writing before the general meeting.
- (5) The general assembly must be convened at least once a year as well as when the interest of the association so requires. The invitation shall be made by the chair or, if absent, the vice-chair or by the management of the office in writing, which includes email, with notification of the provisional agenda at least 3 weeks in advance.
- (6) Members may submit additions to the agenda to the chair in writing, stating sufficient grounds for the same, at the latest two weeks before the scheduled meeting date. Requests received later may be treated as urgent requests and may be included on the agenda by a majority of $\frac{3}{4}$ of the voting members present at the general meeting. Exceptions to this rule are any amendments to these statutes and other decisions of importance to the association. For all agenda items submitted by members, the board will give an opinion at the general meeting.
- (7) The general meeting is chaired by the president; if unable to attend, then by the vice president.
- (8) The general meeting has a quorum if at least 50% of the voting members are present in person or in a digital way (e.g. via phone or video conference) or have properly assigned their voting rights to another member per §9 (4) above.
- (9) Unless otherwise stipulated herein or as required by law, the general meeting decides by a simple majority of the valid votes cast. Abstentions and invalid votes are not counted. In the case of a tie, the vote of the president or in his absence, the vote of the vice-president decides. Decisions are generally made by open ballot or on paper ballots if the chair of the meeting deems this to be necessary, unless these articles or the law stipulate otherwise.

§10 The duties of the general assembly

The general meeting has the following statutory duties:

- Elect and recall members of the board;
- Receive the annual report and the annual accounts from the board and discharge the board;
- Approve the budget;
- Decide on amendments to these statutes or on dissolution of the association;

- Decide on motions submitted by the board, members, working groups, or the scientific advisory board and the duties assigned to it herein;
- Decide to adopt rules of procedure beyond these statutes; the board may then take purely editorial changes to these rules and also make changes to aspects that do not fall within the duties of the general meeting as assigned herein or by law;
- Set the amount and due date of membership fees;
- Decide on the admission of new observers and members, conversion of membership, and exclusion appeals;
- Decide on amendments and additions to the agenda.

§11 Board

- (1) The board consists of at least three and no more than five representatives of the member organisations. A maximum of 1 person from any member organisation may be nominated for election to the board.
- (2) From the persons nominated by the member organisations, the following offices are elected:
 - a. President
 - b. Vice president
 - c. Treasurer
 - d. And a maximum 2 other members (extended board)
- (3) The persons elected should come from different countries if possible. They are elected for a period of 3 years and may stand for re-election.
- (4) If a member of the board leaves before the end of his/her term, the board may choose from the ranks of the delegates of the member organisations another member to serve until the next general assembly.
- (5) The board manages the affairs of the association. The board is responsible for all matters of the association, unless assigned herein or by law to the general assembly. The board is responsible for the administration of the association's assets and the execution of its decisions. It may set up a business office and hire staff to handle day-to-day business, if deemed necessary and if the financial situation of the association so permits.
- (6) The association is represented by the president, the vice president and the treasurer, each on his or her own, both in and out of court per §26 of the German Civil Code (BGB). Internally, the vice president and treasurer are only authorised to represent the association if the first chair is prevented from exercising the office or has authorised the vice president or treasurer to act on his/her behalf.
- (7) The board generally takes its decisions in meetings chaired by the president or by the vice president if the former is unable to attend, with two weeks' notice stating the agenda. This notice period may be waived by the unanimous decision of all board members. The board has a quorum if three of its members are present in person or by teleconference or have previously cast their votes in writing. It decides with the majority of valid votes cast.

- (8) Abstentions and invalid votes are not counted. In the case of a tie, the vote of the President and in his absence the vote of the vice-president decides. The board meets in person at least twice a year or, if not otherwise possible, by teleconference. In urgent cases, a board member may propose motions to the board for its approval by written vote, with an appropriate response period of at least 7 days to vote. Again, this minimum response time may be reduced to two days by the unanimous vote of all board members. Resolutions voted on outside regular board meetings and their results are to be attached to the minutes of the next board meeting.
- (9) A board meeting must be convened within one month if at least two members of the board request it, stating the reasons in writing (including email).
- (10) The board may appoint advisory boards and working groups to fulfil association tasks. Further details are regulated by §§12 and 13 of these statutes. The board may set its own rules of procedure for its work.
- (11) The board is liable for damage to members and to the association caused by its actions, but only if done with intention. This also applies if the board receives remuneration for its activity.
- (12) If the board is obliged to compensate another person for damage caused by the board in the performance of its duties, it may ask the association to indemnify it from said liability. Clause 1 does not apply if the damage was caused intentionally.

§12 Working groups

- (1) For the preparation and implementation of individual projects, the board or the general meeting may set up working groups.
- (2) In the working groups, the members develop work priorities and options for action for the association. A working group may only make its work public after consultation with the board. A working group may make a legally binding representation of the association only with express permission.
- (3) The membership, chair, working method, dissolution, and further regulations on the working groups are contained in the rules of procedure of the association adopted by the general assembly.

§13 Scientific advisory board

The association may convene a scientific advisory board to support its work. Its members are named by the general meeting. The scientific advisory board advises the association primarily on medical and research-related issues and assists in the selection of research projects worthy of association support.

If necessary, further details can be set forth in rules of procedure to be adopted by the general assembly.

§14 Minutes

Minutes shall be taken of all meetings of the association's bodies and signed by the chair of the meeting and the recording secretary.

The recording secretary is named at the beginning of any meeting by the first chair or, if absent, by the second chair or treasurer.

The minutes are to be signed by the first chair or his/her representation and the recording secretary and sent to the members of the body without delay by post, fax, or electronic means.

§15 Amendments to these statutes, change to the association's purpose

An amendment to these statutes or the purpose of the association is made by a resolution of the general assembly with a majority of $\frac{3}{4}$ of the valid votes cast.

Abstentions and invalid votes are not counted.

The board is authorised to make such changes to these statutes which are merely editorial in nature or which are required by a supervisory, judicial, or fiscal authority without prior approval by the general assembly. The members are to be informed immediately of these changes.

§16 Dissolution of the association

- (1) The dissolution of the association takes place by resolution of an extraordinary general meeting convened exclusively for this purpose. The resolution requires a majority of three-quarters ($\frac{3}{4}$) of the valid votes cast. Abstentions and invalid votes are not counted.
- (2) The general meeting would then appoint three liquidators to wind down the association's affairs.
- (3) In case of dissolution of the association or if its tax-privileged purpose ceases to exist, the assets of the association shall fall to a legal entity under public law in Germany or the EU or another tax-privileged body in Germany or the EU, which also supports public health care in the area SMA or neuromuscular diseases and/or the promotion of science and research in the field of SMA or neuromuscular diseases according to §2 of these articles.
- (4) This organisation is selected by the general meeting with a simple majority of votes at the same meeting that decides on the dissolution of the association and the appointment of the liquidators.

Warsaw, 12th October 2019