

The Statutes of Národní organizace pro ověřování léčiv, z.s.

Recitals – Used Terms

- (i) **EMVO - European Medicines Verification Organisation** – a non-profit organisation founded by European interest groups in order to protect the legal supply chain against falsified Medicinal Products. The goal of the organisation is also to manage the European repository.
- (ii) **European Repository** – it shall be linked to national or regional data repositories and shall serve as a platform for verification of the authenticity of Medicinal Products anywhere in any supply chain in the European Economic Area (hereinafter referred to as the “EEA”). This European Repository and the national repository are also collectively referred to as the “**European Medicines Verification System (EMVS)**” or the “**System**”).
- (iii) **Medicinal Product** – a medicinal product that must bear safety features in compliance with the Directive (see (x) below) and with related delegated acts adopted pursuant to the Directive (in particular the Implementing Regulation see (ix) below) in the Czech Republic.
- (iv) **MAH (Marketing Authorisation Holder)** – a marketing authorisation holder with respect to Medicinal Products.
- (v) **Extraordinary Event** – any incident creating suspicion that some Medicinal Product may be falsified or that the System may have been compromised or that some other problem occurred and prevents a usual or continuous use of the System. An Extraordinary Event may be e.g. a failed verification/check (because the unique identifier is not in the System or has already been registered as issued or decommissioned, e.g. because a production batch was recalled), attempted access by an unauthorised person or any other activity indicating that the System was compromised.
- (vi) **NOOL or Organisation** – Národní organizace pro ověřování léčiv, z.s. (National Medicines Verification Organisation) – a national non-profit legal entity founded by regular founding members in order to protect the legal supply chain against falsified Medicinal Products by creating and managing the national data repository linked to the European Repository. The European Repository shall be linked to national or regional repositories and shall serve as a platform for verification of the authenticity of Medicinal Products anywhere in the supply chain in the EEA.
- (vii) **NMVS – National Medicines Verification System** – a system that comprises of the national repository linked to the European Repository and serves as a platform for verification of the authenticity of Medicinal Products in the Czech Republic.
- (viii) **Verification** – verification that a Medicinal Product exists in the national database with information identical to that on the 2D matrix of the barcode on the packaging.
- (ix) **Implementing Regulation** – Commission delegated Regulation EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
- (x) **Directive** – Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

- (xi) **Manufacturer** – for the purposes of this document, a Manufacturer means a holder of authorisation to manufacture Medicinal Products, i.e. both a manufacturer and a parallel distributor of Medicinal Products that repackages Medicinal Products; a Manufacturer does not mean suppliers or sub-suppliers involved in the production process but not responsible for marketing Medicinal Products. To eliminate any doubts, a Manufacturer that hired a supplier or sub-supplier to perform production activities on its behalf shall be considered a production authorisation holder.
- (xii) **ČAFF** – Česká asociace farmaceutických firem (Czech Association of Pharmaceutical Firms), an interest group of legal entities, with its registered seat at Na Zlíchově 18, Hlubočepy, 1520 00 Prague, IN: 70896399, registered in the Register of Associations kept by the Municipal Court in Prague under ref. No. L 58572.
- (xiii) **AIFP** – Asociace inovativního farmaceutického průmyslu (Association of Innovative Pharmaceutical Industry), with its registered seat at Pobřežní 620/3, Karlín, 186 00 Prague, IN: 70970173, registered in the Register of Associations kept by the Municipal Court in Prague under ref. No. L 58517.
- (xiv) **AEDL** – Asociace evropských distributorů léčiv (Association of European Medicines Distributors), with its registered seat at náměstí Smiřických 42, 281 63 Kostelec nad Černými lesy, IN: 01304216, registered in the Register of Associations kept by the Municipal Court in Prague under ref. No. L 58763.
- (xv) **AVEL** – Asociace velkodistributorů léčiv – AVEL, z.s. (Association of Medicines Wholesalers), with its registered seat at Pelikánova 32/7, Liboc, 162 00 Prague 6, IN: 03195651, registered in the Register of Associations kept by the Municipal Court in Prague under ref. No. L 61076.
- (xvi) **ČLnK** – Česká lékárnická komora (Czech Chamber of Pharmacists), with its registered seat at Rozárčina 1422/9, P.O. BOX 64, 140 02 Prague 4.
- (xvii) **SÚKL** - Státní ústav pro kontrolu léčiv (State Institute for Drug Control), with its registered seat at Šrobárova 48, 100 41 Prague 10.
- (xviii) **Civil Code** – Act No. 89/2012 of Coll., the Civil Code, as amended.
- (xix) **Loan Agreement** – an agreement on the provision of a loan, which is going to be concluded between AIFP and ČAFF as a lenders; the lenders – AIFP and ČAFF, shall participate in the total loan in the amount settled in Agreement between lenders, based on their market share according to SÚKL's data from 2015.
- (xx) **NMVS User** – an MAH/Manufacturer that is or is not an NOOL member and, in compliance with the Directive (Article 54a (2, e) and the Implementing Regulation (Item 28 of the Preamble and Article 53 (5)) must bear the cost of the System.

Article I

Basic Provisions

- (1) Name of the Organisation: Národní organizace pro ověřování léčiv, z.s.
- (2) Registered seat of the Organisation: Prague.

Article II

Purpose

- (1) The purpose of NOOL is to prevent, in compliance with the Directive and the Implementing Regulation, the entry of falsified Medicinal Products into the legal supply chain in particular by creating, managing and operating the NMVS in order to achieve and ensure cooperation between the NOOL members and the NMVS Users and competent entities and authorities in implementing the Directive, adopting the Implementing Regulation and ensuring the proper operation of NOOL
- (2) In view of its purpose specified in Paragraph 1, NOOL shall in particular:
 - a. specify the criteria of a tender for an IT services provider that shall create and commission the NMVS and ensure the proper functioning of the System as well as call for such tenders, select the winner and execute relevant contracts;
 - b. supervise the creation and operation of the NMVS;
 - c. create standard operating procedures (SOP) for:
 - i. the regular operation of the NMVS and its link to the European Repository;
and
 - ii. the identification and processing of Extraordinary Events;
 - d. set up technical standards and ensure a high-quality NMVS with regards to the data interface of the national data repository, data purity, the accessibility and quick response of the NMVS, appropriate security level, etc.;
 - e. define the requirements for accessing the national data repository;
 - f. manage IT and contractual and human interfaces between the national repository and the European Repository;
 - g. provide SÚKL with access to NOOL/the NMVS in compliance with the delegated acts arising from the Directive;
 - h. specify the rules of the ownership and protection of intellectual property rights to software developed for the operation of the national data repository in compliance with the Implementing Regulation;
 - i. provide regular reports on the activities of NOOL and its members concerning in particular the functioning and performance of the NMVS;
 - j. ensure and implement control mechanisms in order to verify whether or not the NMVS evaluates in the interest of patient safety and in compliance with the current requirements of the healthcare system in the CR and the EU, which also includes regular audits of the repository in order to verify its compliance with the requirements of applicable legal regulations;

- k. collect fees starting on 9 February 2019 in compliance with Article V of these Statutes, which shall also cover the operating costs of NOOL and the NMVS and cover any potential sanctions imposed on the Organisation by state authorities and future risks;
 - l. provide assistance to the NMVS Users for a reasonable fee decided on for each upcoming calendar year in the Board of Directors' resolution;
 - m. execute contracts and other financial and payment agreements necessary for the operation of the NMVS;
 - n. cooperate with national regulatory authorities that have rights of access and supervision over the practical implementation and running of the NMVS; and
 - o. provide services to partners (competent entities and authorities) or third parties in connection with the operation of the NMVS and in compliance with the purpose of NOOL.
- (3) NOOL may also perform other activities, in particular in view of fulfilling the purpose of NOOL specified in Paragraph 1.
- (4) NOOL shall proceed with due care, in particular shall obtain funds in a way to ensure – while keeping in mind the non-profit nature of NOOL – a permanently sustainable and maximum self-funding of NOOL's activity. NOOL shall approve the next year's budget by the end of the current year and shall observe the budget or, if necessary, shall immediately propose budget changes to the General Meeting for approval. NOOL is obliged to proceed in compliance with the Directive and the Implementing Regulation.

Article III

Membership

- (1) The NOOL members are either regular or affiliates members, depending on the type of their membership.
- (2) ČAFF, AIFP, AEDL, AVEL and ČLnK are NOOL's regular founding members. Any Manufacturer or MAH, which exists as an independent entity and was accepted as an additional regular member after the foundation of the Organisation by the Board of Directors of the Organisation, can become an additional regular member after 9 February 2019, provided that such a member met the requirements laid down in these Statutes. This does not apply to SÚKL that can become an additional regular member after 9 February 2019 based on its acceptance by the Board of Directors of the Organisation and provided that it met the requirements laid down in these Statutes.
- (3) Any independent entity with a legitimate interest in implementing the purpose of the Organisation, especially a distributor, Manufacturer, MAH and entity authorised to dispense Medicinal Products, including interest groups representing these entities, can become an affiliated member, provided that it met the requirements laid down in these Statutes and was accepted as an affiliated member by the Board of Directors of the Organisation after the foundation of the Organisation.
- (4) The membership in the Organisation is created by the decision of the Board of Directors of the Organisation to accept a member that duly delivered its application to the Board of Directors of the Organisation. When filing its membership application, the applicant must prove the

number of MAHs it includes or represents and must immediately report in writing any change in such information to the Board of Directors of the Organisation. The Applicant must prove such facts with data kept by SÚKL or with relevant powers of attorney granted for registration purposes and information based on data kept by SÚKL. The Board of Directors of the Organisation shall decide whether the applicant shall become a regular or affiliated member.

- (5) The Board of Directors of the Organisation shall decide about the acceptance of a regular or affiliated NOOL member at its very next meeting after the receipt of a written membership application. The applicant shall be informed in writing about whether or not it was accepted as an NOOL member within 10 calendar days of the decision of the Board of Directors of the Organisation.
- (6) The NOOL membership is terminated:
 - a. by written membership termination notice delivered to the Board of Directors by the member that wishes to terminate its membership. Such notice shall come into force upon its delivery to the Board of Directors;
 - b. by dissolution of a member;
 - c. by the Board of Directors' decision in the case that an Organisation member grossly breached its obligations specified in these Statutes; for the purposes of this provision, a gross breach does not mean a default on a membership fee;
 - d. by a default on a membership fee. In the case that an NOOL member does not pay its membership fee within the time-limit specified in Article V of these Statutes and fails to pay it even after a reasonable time-limit provided by the Board of Directors in a second delinquent payment reminder. The payment time-limit must always be at least 14 calendar days after the delivery of the reminder.
- (7) The Board of Directors of the Organisation must keep a list of NOOL members, which is public and available at NOOL's website. The chair of the Board of Directors of the Organisation shall include or delete members from the list immediately after such a fact was approved by the Board of Directors. The inclusion and deletion of members from the list is of a declaratory nature.
- (8) The membership in the Organisation does not pass onto the legal successor of a member.

Article IV

Rights and Obligations

- (1) Regular members have the following rights and obligations:
 - a. the right to participate, make proposals and vote (in compliance with Article VII of these Statutes) at the sessions of the General Meeting in compliance with these Statutes;
 - b. the right to vote and be elected to the Board of Directors of the Organisation and other NOOL bodies in compliance with these Statutes;
 - c. the right to nominate members, the vice-chair and the chair of the Board of Directors in compliance with Article VIII of these Statutes;
 - d. the right to participate at the meetings of the Board of Directors;
 - e. the right to participate in workgroups and ad hoc meetings;

- f. the right to request an independent audit on the security and performance of the NMVS and the running of NOOL, provided that such audits are performed by a qualified entity (in particular an auditor in the given field or its representative), in reasonable intervals and at the expense of the member requesting the audit;
 - g. the obligation to pay an annual membership fee in compliance with and under the conditions specified in Article V of these Statutes as well as other fees specified in these Statutes or decided on by the General Meeting;
 - h. the obligation to act in compliance with these Statutes and other internal regulations of NOOL;
 - i. the obligation to inform the Board of Directors of the Organisation in writing about the number of MAHs they include and represent and must prove such a fact with data based on information kept by SÚKL or provide powers of attorney granted for registration purposes and information based on the data kept by SÚKL, by 31 January of each calendar year, during which they are members; and
 - j. the obligation to refrain from any commercial use of data, which were created during the interaction with NSOL and data kept in audit trail; and
 - k. other rights or obligations decided on by the General Meeting in compliance with these Statutes.
- (2) Affiliated members have the following rights and obligations:
- a. the right to be invited and participate in a session of the General Meeting as a non-voting observer;
 - b. the right to comment on NOOL's activities at the General Meeting;
 - c. the obligation to act in compliance with these Statutes and other internal regulations of NOOL; and
 - d. the obligation to refrain from any commercial use of data, which were created during the interaction with NSOL and data kept in audit trail; and
 - e. other rights or obligations decided on by the General Meeting.

Article V

Membership and User Fees

- (1) A regular NOOL member must pay an annual membership fee in the amount proposed by the Board of Directors and approved by the General Meeting (hereinafter referred to as the **"Membership Fee"**). The Membership Fee shall cover the cost of services connected with the organisation and management of the operation of NOOL, including the operating cost of NOOL. First Membership Fee is going to be determined during the founding General Meeting of NOOL.
- (2) In compliance with the Directive and the Implementing Regulation, each NMVS User must bear the cost of the System, which means:
- a. to pay NOOL, based on a separate contract executed between NOOL and the User, a user fee in the amount proposed by the Board of Directors and approved by the General Meeting (hereinafter referred to as the **"User Fee"**). The User Fee shall be paid at the beginning of each calendar year of using the NMVS system and shall be used to

cover the cost of the NMVS system in the given calendar year, to cover NOOL's operating costs (i.e. the cost of services connected with the organisation and management of the operation of NMVS and NOOL) as well as to cover EMVO's payments for EU HUB and to cover payments to the Future Risks Fund. A part of the User Fee specified in Article XI (5, b) shall be paid into the Future Risks Fund;

- b. to pay NOOL, based on a separate contract executed between NOOL and the User, a registration (one-off) fee, the amount of which shall depend on the time of payment (hereinafter referred to as the "**Registration Fee**"). The Registration Fee shall be paid only once upon registration to NMVS and shall be used to cover the cost of system implementation, to pay off the Loan Agreement, including interest, and to make payments into the Future Risks Fund. A total of 3% of the Registration Fee shall be used to make first payments into the Future Risks Fund.
- (3) The membership of affiliated NOOL members is, in compliance with Article 31 (3) of the Implementing Regulation, free of charge.
- (4) The membership of a regular NOOL member that does not pay the Membership Fee in compliance with the conditions in these Statutes shall be terminated under the conditions laid down in Article III (6, d) above.

Article VI

General Meeting

- (1) The General Meeting comprises of regular members only and represents the highest body of NOOL. The General Meeting in particular:
- a. sets NOOL's general policies, goals, procedures, directions, methods and activity to achieve its purpose;
 - b. determines which decisions can be delegated to the Board of Directors of the Organisation;
 - c. approves next year's budget and its potential changes;
 - d. approves annual financial statements and annual activity and management reports (hereinafter referred to as "**Annual Reports**");
 - e. approves changes in the Statutes;
 - f. elects and removes the chair, the vice-chair and members of the Board of Directors of the Organisation, except for the members appointed by SÚKL;
 - g. specifies the authorisations of the chair, the vice-chair and members of the Board of Directors;
 - h. selects an auditor and authorises the Board of Directors to execute and terminate a contract for the services of such an auditor;
 - i. removes a member of the Organisation in compliance with Section 239 et sequentur of the Civil Code;
 - j. decides about the dissolution, dissolution implementation and liquidation of NOOL;
 - k. approves the amount and due date of the Membership Fee and User Fee proposed by the Board of Directors; and
 - l. makes any other decisions that are not delegated to the Board of Directors.

- (2) The General Meeting is convened by a written invitation of the chair of the Board of Directors of the Organisation at least once a year; however, no later than six months after the end of the previous calendar year. The General Meeting exercises its rights at its sessions in compliance with these Statutes.
- (3) Extraordinary sessions of the General Meeting must be convened based on a written request of at least one regular member no later than two months after such a request was delivered to the Board of Directors of the Organisation or based on a decision of the Board of Directors in compliance with the Statutes.
- (4) Sessions of the General Meeting shall be chaired by the chair of the Board of Directors of the Organisation or, if the chair is absent, by the vice-chair of the Board of Directors of the Organisation or, if the vice-chair is absent, by another member of the Board of Directors of the Organisation.
- (5) The invitation must include the agenda, date, time and location of the General Meeting and must be sent out by letter, e-mail or any other mean of communication in the form of a written at least 55 calendar days before the General Meeting.
- (6) After having received the invitation sent to the NOOL members in the manner and within the time-limit specified in Paragraph 5 above, the regular NOOL members agree to inform each other about the number of MAHs, which they represent, by a written affidavit delivered to the address of the other regular members shown in the list of the NOOL members no later than 40 days before the General Meeting. Each regular NOOL member has the right to raise written and justified objections about the wrong number (including name) of MAHs in an affidavit and must send such objections to the other regular members no later than 30 days before the General Meeting. In the case that no regular member exercises this right or delivers its written objections after the time-limit, it shall be assumed that the information in the affidavit of each regular member is correct and true. In the case that a regular member exercises this right specified in the second sentence of this paragraph, the regular member, against which the justified objection was raised, must send a written power of attorney, which shall prove its authorisation to represent the MAH in question, to the address of the other regular members no later than 20 days before the General Meeting. In the case that such a power of attorney or its simple copy is not delivered to the other regular members within the time-limit specified in the previous sentence, the vote of this MAH at the General Meeting shall be disregarded.
- (7) Sessions of the General Meeting are non-public for persons other than the NOOL members.
- (8) Each member has the right to grant a power of attorney to a third party to represent the member in exercising its rights, performing its obligation and voting at the General Meeting. The principal's signature in the power of attorney must be certified. The attorney can represent only one regular member at the General Meeting.
- (9) Every regular member will have the right of veto in the case that the General Meeting decides about a change in the requirements of the association (regardless of whether such requirements were specified based on the Directive or the Implementing Regulation or any other implementing regulation) in agreed principles regulating data access and management, provided that such a change concerns the data of such a member. The right of veto can be exercise only on the condition that the facts specified in the previous sentence were duly discussed by all regular members present at the General Meeting and the outcome of exercising the right of veto was in compliance with effective legal regulations.

Article VII

Resolutions of the General Meeting

- (1) The General Meeting has a quorum if the present regular members represent four-fifths of all votes determined in compliance with these Statutes. A substitute General Meeting shall be convened based on the rules for the convocation of a regular General Meeting (see Article VI) and must be convened within 60 days of the original General Meeting.
- (2) Unless otherwise specified in these Statutes, resolutions of the General Meeting must be passed by at least four-fifths of the votes of present members.
- (3) Each regular member has a vote for each MAH it represents in compliance with its affidavit and the procedure specified in Article VI, Paragraph 6 above, either by virtue of the membership of the actual regular member or based on a special power of attorney, which has priority in such a case. An MAH or Manufacturer, who is a regular member, has one vote, and this vote does not belong to a regular member, of which the MAH is a member. An MAH or a Manufacturer, which is a regular member, can authorise another regular member to vote on its behalf. This MAH or Manufacturer cannot vote independently until such a power of attorney is revoked. AVEL and ČLnK have each one vote based on this paragraph.
- (4) With the exception of SÚKL, AVEL and ČLnK, a regular member must prove the number of represented MAHs in the manner and in compliance with Article VI (6) above. The number of votes at the General Meeting corresponds to the number of MAHs proven in the manner specified in Article VI (6) above.
- (5) Only the lenders, which are specified in the Loan Agreement and are the NOOL members, can vote on a regular, extraordinary or substitute General Meeting's resolutions concerning the suppliers selected to setup, implement and operate the NMVS, , concerning the Loan Agreement and concerning the approval of NOOL's annual expense plan. The resolutions specified in the previous sentence must be passed by four-fifths of the votes. This provision shall no longer be in force after the loan, which is the subject-matter of the Loan Agreement, is paid off.
- (6) When the members of the Board of Directors are elected at the General Meeting, AIFP has the right to nominate three members of the Board of Directors, ČAFF has the right to nominate two members of the Board of Directors and AEDL, AVEL and ČLnK have each the right to nominate one member of the Board of Directors. Each of these regular members can nominate these persons without the consent of the other regular members. All members of the Board of Directors are elected at the General Meeting in compliance with Paragraphs 2 and 3 of this article. Other three members of the Board of Directors are nominated by SÚKL from among its employees; these members are not subject to approval by any body of NOOL and are elected for the same office term as the other members of the Board of Directors elected by the General Meeting and as of the same day the General Meeting elected the other members of the Board of Directors. SÚKL shall inform the Board of Directors of the Organisation about the nomination of its representatives for the Board of Directors by a written notice sent by registered mail and/or e-mail at least seven days before the General Meeting. In the case that SÚKL does not, for any reason, deliver the notice within the time-limit specified in the previous sentence or nominates less than three members of the Board of Directors, such members of

the Board of Directors shall be elected at the General Meeting from among the persons present at the General Meeting and satisfying the requirements for the office of member of the Board of Directors. In the case that the employment of the person nominated by SÚKL is terminated during his/her office term, SÚKL shall replace such a person for the remaining office term by another employee and shall inform the Board of Directors of the Organisation by a written notice delivered to the Board of Directors of the Organisation within seven days of termination of the employment of the person who held the office of member of the Board of Directors.

- (7) The chair of the Board of Directors and the vice-chair of the Board of Directors are elected from among the members of the Board of Directors in the manner specified in Paragraphs 2 and 3 of this article.
- (8) Resolutions concerning the dissolution of NOOL or the removal of an NOOL member require at least four-fifths of all votes of regular members.
- (9) The resolutions of the General Meetings must be recorded in writing. The minutes of such resolutions must be drawn up and signed by the chair of the General Meeting immediately after the General Meeting and formally approved immediately after the end of the General Meeting. The minutes – except for the minutes that must be approved by a notary public - and its amendments shall be kept at NOOL's registered seat, in the original form or in a secured electronic form, provided that provided that such reproduction guarantees data permanency, legibility, integrity and trueness. The members can read the minutes from the General Meeting at NOOL's registered seat or can receive their copy upon request.

Article VIII

Board of Directors

- (1) The Board of Directors is a statutory and collective body of the Organisation. The Board of Directors has 11 (in words: eleven) members elected by the General Meeting for a two-year period, unless SÚKL exercises its right and nominates one to three members of the Board of Directors from among its employees; these persons are not subject to approval by any body of NOOL and are always elected for the same office term as the other members of the Board of Directors elected by the General Meeting and as of the same day the General Meeting elected the other members of the Board of Directors. This does not prejudice the fifth, sixth and seventh sentence of Article VII (6).
- (2) A member of the Board of Directors can be re-elected. A member of the Board of Directors shall be receive 2.400 CZK a year.
- (3) Meetings of the Board of Directors are non-public for persons other than the members of the Organisation, their representatives or persons invited to the meetings by the Board of Directors.
- (4) An elected member of the Board of Directors that is a legal entity must appoint an individual who shall represent the entity and shall perform this office in NOOL.
- (5) The liability of the members of the Board of Directors shall be governed by Section 159 of the Civil Code.
- (6) The authorisation of a member of the Board of Directors to perform office shall end:

- a. by resignation - 30 days after the written resignation notice was delivered to the Board of Directors;
 - b. by expiry of the office term;
 - c. by death;
 - d. by termination of a contract or employment relationship between a member of the Board of Directors and a regular member represented by the member of the Board of Directors;
 - e. by dissolution of a member – legal entity; or
 - f. by the General Meeting's resolution to remove a member from office.
- (7) The Board of Directors must make sure that NOOL performs its activity in compliance with these Statutes, applicable legal regulations and the resolutions of the General Meeting.
- (8) The Board of Directors exercises its rights in the following areas and scope:
- a. keeps the minutes from all meetings of the Board of Directors and informs all regular members of the Organisation about the resolutions of the Board of Directors;
 - b. prepares budgets and financial statements, keeps and manages the bank account of the Organisation and passes any other resolutions necessary for the proper functioning of NOOL in compliance with the Organisation's financial plan for the relevant calendar year that had been passed by the General Meeting. In the case that the General Meeting does not approve the Organisation's financial plan for the relevant calendar year, the Board of Directors shall proceed in a way so that monthly expenses would not exceed one-twelfth of the financial plan approved by the General Meeting for the previous calendar year;
 - c. performs legal acts on the behalf of the Organisation that are in compliance with these Statutes and ensure the proper functioning of the Organisation in compliance with the previous annual financial plan, the internal regulations of the Organisation and the purpose of the Organisation based on these Statutes;
 - d. presents recommendations concerning the Membership Fees and User Fees, in particular proposals of their amount and due date, to the General Meeting;
 - e. provides the General Meeting with recommendations concerning the allocation of the User Fees charged by NOOL to production authorisation holders and/or Marketing Authorisation Holders for using the NMVS;
 - f. accepts members in compliance with Article III (4);
 - g. supervises the implementation of the Directive and the Implementing Regulation, regularly monitors NMVS performance, Extraordinary Event management, operational matters, structure management and data access security and reports any findings to the General Meeting, establishes and disestablishes any committees and workgroups and determines the purpose and structure of such committees and workgroups and the conditions of their financing in compliance with the financial plan;
 - h. has the right to decide about draws from the Future Risks Fund.
- (9) The Board of Directors meets as necessary in order to manage NOOL; however, no less than three times a year. The invitation to a meeting of the Board of Directors must be sent out to its members by e-mail, by letter or in any other appropriate manner at least 10 calendar days before the meeting. In some urgent cases explained by the chair of the Board of Directors, this time-limit can be reduced to five calendar days. The meetings shall take place in the registered seat of NOOL or in any other location specified in the invitation. The meetings of the Board of

- Directors shall be chaired by the chair of the Board of Directors or, if the chair of the Board of Directors is absent, by the vice-chair or any other present member of the Board of Directors.
- (10) The Board of Directors has a quorum if an absolute majority of its members or their representatives, based on a written power of attorney with the principal's certified signature, is present at the meeting.
- (11) A simple majority of the votes of all members of the Board of Directors is required to pass a resolution of the Board of Directors. Each member of the Board of Directors has one vote.
- (12) Every regular member of the Board of Directors has the right to give any other member of the Board of Directors or any other person a signed power of attorney to vote at a meeting of the Board of Directors and to send it to any member of the Board of Directors by e-mail. The agent can have only one power of attorney. This does not prejudice the responsibility of the delegating member.
- (13) The meetings of the Board of Directors can be held in the form of a conference call or videoconference. The members of the Board of Directors can vote on a specific draft resolution electronically, e.g. the chair of the Board of Directors can send out an e-mail specifying the time-limit for voting on the draft resolution.
- (14) All resolutions of the Board of Directors must be recorded in writing and approved and signed by the chair of the Board of Directors. Resolutions passed at the meeting of the Board of Directors and recorded in writing and minutes from the meetings of the Board of Directors shall be kept at the registered seat of NOOL, in the original form or in a secured electronic form, provided that such reproduction guarantees data permanency, legibility, integrity and trueness. The members can read the minutes from the General Meeting at NOOL's registered seat or can receive their copy upon request. The members of the Board of Directors can read the minutes and written resolutions at NOOL's registered seat or can receive their copy upon request.
- (15) The chair of the Board of Directors together with another member of the Board of Directors or the vice-chair of the Board of Directors together with another member of the Board of Directors is authorised to act on behalf of, and represent, the Organisation with respect to third parties.
- (16) The qualifying requirement for a person to become a member, the chair or the vice-chair of the Board of Directors of the Organisation is that such a person must be a member of the statutory body or an employee of a regular member, with the exception of the members of the Board of Directors representing SÚKL.

Article IX

Implementing Regulations

- (1) To ensure the compliance of the procedures of NOOL and the activity of its members with these Statutes, the General Meeting authorised to implement internal regulations. The purpose of these regulations is to specify these Statutes and the practical ways of functioning and financing of NOOL.
- (2) Only the General Meeting is authorised to decide on a change in the internal rules and regulations, including these Statutes, based on the Board of Directors' proposal.

- (3) Once a year, the Board of Directors of NOOL shall evaluate the topicality and compliance of all internal regulations with these Statutes and shall propose to the General Meeting changes that are necessary for the further proper functioning of NOOL.

Article X

Chair and Vice-Chair of the Board of Directors

- (1) The chair of the Board of Directors coordinates the activity of the Board of Directors and makes sure that the Board of Directors performs its obligations. The chair of the Board of Directors shall chair the meetings of the Board of Directors and the sessions of the General Meeting and shall perform the tasks set by both these bodies. The chair of the Board of Directors shall in particular:
- a. convene the sessions of the General Meeting and the meetings of the Board of Directors;
 - b. implement the policies decided on by the Board of Directors;
 - c. propose relevant plans to the Board of Directors and manage the resolutions of the Board of Directors;
 - d. set up and maintain a regular communication with all members; and
 - e. represent NOOL with respect to third parties, including state and regulatory authorities.
- (2) In the case of a long absence (i.e. more than three weeks) of the chair of the Board of Directors, the vice-chair of the Board of Directors shall exercise such rights of the chair of the Board of Directors and perform such obligations of the chair of the Board of Directors as specified in these Statutes.

Article XI

Fiscal Year. Financial Statement. Budget. Audit

- (1) The fiscal year of NOOL is a calendar year that starts on 1 January and ends on 31 December, with the exception of the first fiscal year that starts on the day the Organisation was founded and ends on 31 December of the relevant calendar year.
- (2) Every year, the Board of Directors shall prepare a financial statement for the previous fiscal year and shall propose an annual financial plan for the following fiscal year. The financial plan must respect balanced management principles, sustainable development and the unconditional and proper performance of the Loan Agreement. The financial statement and the financial plan shall be presented at the session of the General Meeting for approval. Accounting shall be done in compliance with applicable laws, accounting standards and other generally binding legal regulations.
- (3) In compliance with the resolution of the General Meeting, the Board of Directors shall procure an auditor's services for three fiscal years. Such an auditor must be a member of the Chamber of Auditors of the Czech Republic. The auditor shall audit NOOL's financial statements after the end of each fiscal year. After the audit, the auditor shall present a written report with audit findings to the General Meeting and the Board of Directors.

- (4) NOOL is audited every fiscal year.
- (5) **Future Risks Fund:** the Organisation shall create the so-called Future Risks Fund of up to 5 million CZK (in words: five million Czech Crowns) from the User and Registration Fees of all NMVS Users (see Article V (2)) and from the profit of future years after having covered losses of previous years. The Future Risks Fund is created from:
 - a. A part of the Registration Fee in compliance with Article V (2, b); and
 - b. A percentage of the User Fee proposed by the Board of Directors at its last meeting in the calendar year preceding the calendar year in which the User Fee must be paid based on Article V.

The Future Risks Fund shall be created from profit after tax (after the General Meeting approves the financial statement). The Board of Directors shall prepare a proposal for the creation of a part of this Fund in compliance with the Statutes.

The NOOL Board of Directors shall decide about draws from the Fund at its very next meeting after having received the document based on which certain funds should be drawn from the Future Risks Fund.

In the case that a specific amount is drawn from the Future Risks Fund to cover provable damages, payments shall be made into the Future Risks Fund during the following time period to reach the approved amount of 5 million CZK (in words: five million Czech Crowns).

The funds of the Future Risks Fund shall be deposited in NOOL's special escrow account at a bank and can be used only to cover the cost of draws from, and payments into, the Future Risks Fund.

Article XII

Changes in the Statutes

- (1) These Statutes can be changed anytime based on the resolution of the General Meeting. At least four-fifths of the votes of all regular members of the Organisation are required to pass the General Meeting's resolution concerning a change in these Statutes.
- (2) The General Meeting cannot discuss a change in these Statutes if such a change was not included in the agenda shown in the invitation and if at least four-fifths of the votes of all regular members of the Organisation are not duly represented.

Article XIII

Dissolution and Liquidation

- (1) At least four-fifths of the votes of all regular members are required to pass the General Meeting's resolution concerning the dissolution of NOOL.

- (2) Together with the resolution concerning the dissolution of NOOL, the General Meeting shall decide on the appointment of a liquidator and on the way of disposing the liquidation balance.
- (3) In compliance with the Civil Code, NOOL can be dissolved based on a court ruling.
- (4) NOOL shall cease to exist by deletion from the Register of Associations.

Article XIV

Final Provisions

- (1) The legal position of NOOL in the matters not regulated in these Statutes shall be governed by the Civil Code.
- (2) The Organisation has been founded for an indefinite time period.
- (3) In case of any change or replacement of the Directive or the Implementing Regulation leading to a change in the dates or conditions herein, including the date of 9 February 2019, the dates and conditions specified in these Statutes shall be replaced with such changed conditions or replaced dates and shall be announced to the members at the very next General Meeting.
- (4) This full text of the by-laws was approved by the NOOL General Meeting in Prague on 23 August 2018.