

BYLAWS OF THE ASSOCIATION

“ORGANIZAȚIA DE SERIALIZARE A MEDICAMENTELOR DIN ROMÂNIA“

(“THE ROMANIAN MEDICINES SERIALIZATION ORGANIZATION”)

- O.S.M.R. –

A. DEFINITIONS

(1) FOUNDING MEMBERS – Each of the interested parties that are OSMR members are entitled to hold the capacity of a member with full rights, on different sectors/divisions, each sector holding one vote, irrespective of the number of industrial or professional association registered in one sector: (1) research companies in the pharmaceutical field, (2) generic medicines companies, (3) wholesale traders of generic medicines, (4) community pharmacies and hospital pharmacies, as well as (5) parallel distributors of pharmaceutical products.

(2) Research companies in the pharmaceutical field – Associations of Producers, representing the sector of pharmaceutical research.

(3) Generic medicines companies – Associations of Producers of Generic Medicines, representing the sector of pharmaceutical generic and biosimilar companies.

(4) Wholesale traders of generic medicines – Association of Wholesale Distributors of pharmaceutical products, representing the sector of wholesale distributors of pharmaceutical products.

(5) Community and hospital pharmacies – College of Pharmacists from Romania.

(6) Parallel distributors of pharmaceutical products – Associates representing authorized parallel distributors from Romania supplying (“export”) and/or purchasing (“import”) and repacking legitimate European medicines in free circulation.

(7) SEE – European Economic Area.

(8) EMVO – the European Medicines Verification Organisation is an international non-profit association incorporated to implement the European Directive on Falsified Medicines.

(9) EMVS – the European Medicines Verification System for the control of medicines, comprising the Central European System, the National Systems and the interfaces of the parallel producers/distributors, as well as the interfaces with the National Systems.

(10) EMVO Requirements (“URS light”) – an internal document for the incorporation of EMVO (comprises provisions on technical elements, the assignment of costs and other relevant principles).

- (11) EUROPEAN DIRECTIVE ON FALSIFIED MEDICINES - Directive 2011/62/EU from 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, JO L 174, 1.7.2011, p.74 and the REGULATION OF THE DELEGATED COMMISSION (EU) from 2.10.2015 supplementing Directive 2001/83/EC of the European Parliament and Council by the provision of detailed rules for the safety elements appearing of the packaging of medicines for human use.
- (12) EUROPEAN CENTRAL SYSTEM – the EMVO subsystem operating as a portal to remit data to the parallel producers and distributors to the National Systems and enabling the regularization of the data on repackaging activities.
- (13) EXTRAORDINARY EVENT – any circumstance arising the suspicion that a certain product could be falsified, that EMVO is attacked or any other issue preventing the normal and continuous operation of EMVO.
- (14) HOLDERS OF PRODUCTION AUTHORIZATIONS – a term including both the parallel producers and distributors employed in the repackaging process, excluding the contractors and subcontractors involved in the production process, but that are not liable of placing pharmaceutical products on the market. In order to avoid any doubt, a producer hiring contractors or subcontractors to produce on its behalf shall be deemed a Holder of the Production Authorization.
- (15) HOLDER OF THE MARKETING AUTHORIZATION – the company provided on the Marketing Authorization for any products in any country, where the System is applied.
- (16) MEDICINES – those products that have to hold safety elements in accordance with the Directive on Falsified Medicines and subsequently adopted related Delegated Deeds.
- (17) NATIONAL SYSTEM – a system within the European Medicines Verifications Organisation serving as a verification platform for one of the countries by which pharmacies or other stakeholders, such as wholesale distributors from the concerned country, can verify the authenticity of a product. Such terms shall also include an equivalent system of a National System, but operated by EMVO on behalf of the members from the concerned country or a group of several National Systems operated by the concerned members or by EMVO on their behalf.
- (18) OSMR – Asociația “Organizația de Serializare a Medicamentelor din România” (“Romanian Medicines Serialization Organization” Association) or any name given to the legal entity set up by the national coalitions of members to govern a national or regional verification system.
- (19) Bylaws – these Bylaws of the OSMR Association.

B. IDENTIFICATION DATA OF THE FOUNDING MEMBERS OF THE ASSOCIATION

THE FOUNDING MEMBERS are:

1. Asociația Română a Producătorilor Internaționali de Medicamente (ARPIM - Romanian Association of International Medicines Producers), with the registered office in the Bucharest municipality, sectorul 3, Str. Clucerul Udricani nr.18, etaj 2, Romanian legal entity incorporated by virtue of Civil Judgement no. 11 from 18.09.1996 ruled by the Court of Appeal Bucharest – 4th Civil Section, currently registered with the Register of Associations and Foundations of the Court of Law of District 3 Bucharest, Sole Registration Code 8979223, duly represented by Dan Nicolae ZAHARESCU

2. Asociația Producătorilor de Medicamente Generice din România (APMGR – Association of Producers of Generic Medicines from Romania), with the registered office in the Bucharest municipality Cladirea World Trade Center (WTC) intrarea F, et.1, biroul 1.27, sector 1 Bucharest, registered under no. 11/02.03.2009, Sole Registration Code 25332544, duly represented by Viorica-Daniela PREDUNA

3. Asociația Distribuitorilor Europeni de Medicamente (ADEM - Association of European Medicines Distributors), with the registered office in the Bucharest municipality, B-dul Theodor Pallady nr. 287, lot 17, activ C1, Obiectiv 50, parter, biroul nr. 5, sectorul 3, set up by the Decision from 15.01.2014 from File no. 48896/299/2013 of the Court of Law of District 1 Bucharest, registered with the National Register under no. 141/ A/2014, Sole Registration Code 32774646, duly represented by Coralia KREYER

4. Asociația Distribuitorilor și Retailerilor Farmaceutici din România (ADRFR - Association of Pharmaceutical Distributors and Retailers from Romania), with the registered office in the Bucharest municipality, sectorul 1, str. Tipografilor nr. 11-13, Complex S Park, clădirea B3, parter, registered under no. 27/2003/PJ, Sole Registration Code 15348381, duly represented by Gheorghe-Virgil DINULESCU

5. Colegiul Farmaciștilor din România (CFR - College of Pharmacists from Romania), with the registered office in the Bucharest municipality, str. Viitorului nr. 4, sectorul 2, CIF 12131808, duly represented by Razvan PRISADA

mutually agreed to duly set up the ASSOCIATION „ORGANIZAȚIA DE SERIALIZARE A MEDICAMENTELOR DIN ROMÂNIA” hereinafter called the Association and/or OSMR.

The Association shall carry out its activity in accordance with the provisions of Government Ordinance no. 26/2000, the provisions of the Articles of Incorporation and of these Bylaws, by applying the special norms in the field.

CHAPTER I. NAME – REGISTERED OFFICE – SCOPE – TERM - PATRIMONY

Article 1. Name

(1) The name of the Association is ASOCIAȚIA „ORGANIZAȚIA DE SERIALIZARE A MEDICAMENTELOR DIN ROMÂNIA” (abbreviated OSMR), as it results from the name reservation no. 33935/13.04.2017, lodged with the Ministry of Justice, supplemented with approval no. 3317/10.04.2017 issued by the

Ministry of Health – Minister’s Cabinet, changed on the basis of the Agreement regarding the use of the name ASOCIAȚIA „ORGANIZAȚIA DE SERIALIZARE A MEDICAMENTELOR DIN ROMÂNIA” issued under number 20/1619/T.G., dated 05.06.2019 by the General Secretariat of the Government, as well as proof of the availability of the number 175589 dated 13.06.2019, issued by the Ministry of Justice – the Communications and Public Relations Office, approving OSMR using the name ASOCIAȚIA „ORGANIZAȚIA DE SERIALIZARE A MEDICAMENTELOR DIN ROMÂNIA” (THE ROMANIAN MEDICINES SERIALIZATION ORGANIZATION).

- (2) This name shall be provided on all deeds, documents and acts to be drafted in order to carry out the activity.
- (3) The Association is a Romanian legal entity, acting on own behalf and account, both in the country and abroad.
- (4) The Association relies on private initiative and acts on organizational and administrative level, in the light of the applicable Romanian legislation in order to accomplish its object of activity.
- (5) The Association is a non-governmental, autonomous, independent, apolitical and non-profit organization, set up to implement the European Directive no. 2011/62/EU from 8 June 2011 in regard to falsified medicines and its Delegated Regulations.
- (6) The Association shall carry out its activity in accordance with the provisions of Government Ordinance no. 26/2000, the provisions of the Articles of Association and these Bylaws.
- (7) The Association may collaborate, conclude partnerships with or affiliate itself with the approval of the Management Board, to duly set up federations or similar unions, in the country or abroad.

Article 2. Registered Office

- (1) The registered office of the Association is established in the Bucharest municipality, sectorul 1, Calea Floreasca nr. 169, etaj 2.
- (2) By the decision of the Management Board, the registered office may be moved to any address from the country.
- (3) The Association may open representation offices in other localities from Romania or abroad, by observing the legal provisions.
- (4) By the Decision of the Associates’ General Meeting, the Association may set up branches as territorial structures without legal status. Such shall carry out the activities assigned to them by the Association.

Article 3. Scope and Objectives of OSMR

- (1) The scope and objectives of OSMR are the following:
 - a) to incorporate itself, to manage and carry out its activity in accordance with the Requirements of EMVO;
 - b) to cooperate with the stakeholders in implementing the UE Directive on Falsified Medicines and its Delegated Regulations;
 - c) the scope and objectives of the Association shall be fulfilled without limitation, inclusively by:
 - (i) The selection of and contracting with one or more IT suppliers or good reputation and the necessary technical capacity to create the National Medicines Verification System - NMVS;

- (ii) The adherence to the technical standards issued by EMVO in order to ensure general quality;
 - (iii) The implementation of the defined standard operation specifications and procedures:
 - (iv) The current activity of NMVS;
 - (v) The identification and management of Extraordinary Events specific to the National System or generated by the National System, in accordance with the principles established by the OSMR Requirements.
 - (vi) The defining of the terms and conditions governing the access to NMVS that shall be objective and transparent.
 - (vii) The management of IT, contractual and human interfaces between NMVS and the user;
 - (viii) The management of the National System on behalf of the country-wide stakeholders;
 - (ix) The supply of periodic activity reports to the members on issues, such as the operation and performances of NMVS and the generation of statistic reports in order to support the communications regarding the operation of NMVS;
 - (x) The invoicing and collection of membership fees and of any other financial obligations;
 - (xi) The conclusion and management of contracts with users and agreements on prices and payments;
 - (xii) The keeping of the liaison with the country-wide competent authorities with access and control rights in regard to: the practical implementation of NMVS to facilitate the withdrawal of products from the market; other issues in accordance with the EU Directive on Falsified Medicines.
- (2) Such scope and objectives shall be accomplished by taking joint decisions, by organizing actions, opinion exchanges and, as the case may be, by publishing articles in domestic and foreign specialty magazines.
 - (3) The Association may carry out all activities directly or indirectly serving to accomplish the scope, including without limitation: the purchase, sale, lease, possession of all immovable assets and facilities, the setting up of mortgages on such assets, the contracting of loans, the employing of staff, the application of legal procedures and hiring of contractors, as necessary.

Article 4. Term

- (1) The Association was set up for unlimited term.

Article 5. Patrimony

- (1) The patrimony of the Association is on the incorporation date of RON 20,000 in cash, equally deposited by each of the founding members, subscribed and paid up.

- (2) The Association may receive in the patrimony account donations or contributions from legal entities or individuals. The Association may be also funded from other sources with the activity organized in accordance with Government Ordinance 26/2000 in compliance with the decision of the Management Board or the Decision of the Associates' General Meeting, as well as out of funds of other national or international organizations, programs of the European Union or other public or private international institutions.
- (3) The entire patrimony shall be recorded and kept in accordance with the Romanian legislation in the field, on behalf of OSMR and it shall be exclusively used to accomplish its objectives.

CHAPTER II. MEMBERS

Article 6. Member Types

- (1) The Association is made up of the following member types:
 - (a) Members with Full Powers;
 - (b) Members with special status according to the Directive;
 - (c) Affiliated Members with no voting right.
- (2) Members with Full Powers are founding members. The rights and obligations of Members with Full Powers shall be provided herein.
- (3) Affiliated Members are persons accepted with such capacity.
- (4) The acceptance of an Affiliated Member is subject to the procedure provided in Article 8 and it is limited to:
 - (a) Corporate stakeholders, representing users or potential users of NMVS for authentication purposes;
 - (b) Associates from any sector of users that qualified, but chose not to accept the capacity of a Member with Full Rights;
 - (c) Individual producers and holders of marketing authorizations;
 - (d) Wholesale distributors and persons authorized to release medicines to the public.
- (5) Except the provisions from these Bylaws, the rights and obligations of Affiliated Members shall be established by the General Meeting or the Management Board, according to the conditions below.
- (6) Such rights and obligations may differ according to the category in which the Affiliated Member classifies.
- (7) Members are not personally liable for the undertakings of the Association.

Article 7. Rights and Obligations of the Associates

A. Members with Full Powers shall have the following rights and obligations:

(1) RIGHTS

- (a) The right to participate and vote in the sessions of the General Meeting in accordance with these Bylaws and each Member with Full Rights shall be entitled to one vote;
- (b) The right to be elected by their representatives in the management bodies;
- (c) The right to participate in work groups and teams that shall be set up in order to fulfil the objectives of the Association;
- (d) The right to request an independent audit of the security and performance of NMVS, provided such audits are carried out a reasonable time intervals and at the expense of the member, who requested the performance thereof;
- (e) The right to control the activity of the Association. The Management Board shall present annual reports on the manner in which the activities of the Association are carried out and the manner of managing its patrimony;
- (f) The right to access the information concerning the activity of the Association;
- (g) Any other right that shall be decided by the General Meeting or Management Board in accordance with the applicable laws and regulations.

(2) OBLIGATIONS

- (a) The obligation to pay an annual fee as a member with full rights, as well as any other contribution provided in article 10;
- (b) The obligation to observe the provisions hereof and to act in order to fulfil the scope of the Association;
- (c) To notify the management and the members of the Association about issues of interest to accomplish the scope of the Association;
- (d) Any other obligation to be decided by the General Meeting or the Management Board in accordance with the applicable laws and regulations.

B. Affiliated Members shall have the following rights and obligations:

(3) RIGHTS

- (a) The right to be notified about all sessions of the General Meeting and the right to participate in such sessions only as observers;
- (b) The right to be consulted about the activities of ORVM to be established from time to time by the General Meeting;

(c) Any other right to be decided by the General Meeting or the Management Board in accordance with the applicable laws and regulations.

(4) OBLIGATIONS

(a) The obligation to pay an annual fee as an affiliated member to be established according to article 10 below;

(b) The obligation to act in compliance herewith;

(c) Any other obligation to be decided by the General Meeting or the Management Board in accordance with the applicable laws and regulations.

C. **Members with special status** shall have the following rights:

(a) The right to participate with the status of an observer in the sessions of the Management Board.

(b) The right to participate with the status of an observer in the sessions of the General Meeting, where they are entitled to a consulting vote.

(c) Members with special status shall owe no fee to the Association.

Article 8. Admission of Members

(1) The capacity of a member within the Association may be gained based on the adhesion consent expressed by subscription application addressed to the Management Board.

(2) Candidates to adhesion may be admitted by the General Meeting on the recommendation of the Management Board, after such body establishes based on the members' written application that they are eligible in accordance with Article 6 and that they shall accept and adhere to the Bylaws of OSMR and other internal regulations to be adopted.

(3) The stakeholder is entitled to personally defend his application in front of the General Meeting.

(4) The adhesion application is solved by the General Meeting according to its beliefs.

(5) None of the provisions hereof shall be construed in order to grant to a third party rights to the benefit of a candidate.

(6) Members of the Association shall be represented by virtue of a written power of attorney by their legal or conventional representatives (general manager, director, member of the board of directors, president of the board of directors, member of the management board, president of the management board, deputy managing director) and foreign companies acting in Romania shall be represented by their legal or conventional representatives from Romania.

(7) The representation right may be granted by each member, based on a written power of attorney, also to other persons from the management of the concerned company.

(8) The list of proxies of each member shall be remitted to the Management Board on a yearly basis, at the latest by 31 January and it may be amended only in justified circumstances and by notifying the Management Board. In case of failing to remit the annual proxy list, the list remitted in the previous year shall remain valid.

(9) Each member shall pay on subscription a subscription fee, the amount of which shall be established by the General Meeting, on the proposal of the Management Board.

Article 9. Waiver – Suspension – Exclusion – Procedure to Withdraw and Rights of Members

- (1) Any member is entitled to request the termination of the membership, starting as of the end of each tax year, by notifying the Management Board at least 6 months beforehand.
- (2) In case of enforced or voluntary dissolution, insolvency, bankruptcy, termination of activity or other similar events, the membership shall be lost by notification addressed to the concerned member by the President of the Management Board.
- (3) The infringement of any terms or conditions of these Bylaws or of the internal regulations, if the case may be, may result in losing the membership in the Association. In this case, a member may be excluded at any time by the decision of the General Meeting, by the vote of two thirds of the attending or represented Members with Full Powers.
- (4) The exclusion of the member should be provided in the agenda of the concerned meeting and the concerned member shall be able to present his opinion before the vote. Any exclusion decision has immediate effect, unless the General Meeting decides otherwise.
- (5) If the excluded member records outstanding membership fees to the Association or any other outstanding amounts, it shall remain liable to pay the outstanding membership fees also after the exclusion from the Association.
- (6) If, after being accepted, a Member with Full Rights does not longer fulfil the criteria provided Article 6, as determined by the decision of the General Meeting, it shall be entitled to keep the rights rendered to Members with Full Powers for another 1-year period as of the date of the above decision of the General Meeting.
- (7) If the criteria are not fulfilled at the end of the additional year, their capacity of a Member with Full Rights shall be terminated, unless the concerned sector is not by another Member with Full Rights and under the reservation of the decision of the General Meeting, at its discretion.
- (8) Throughout the above 1-year term, the concerned member is bound to pay the annual membership fee.
- (9) Members, who waived the membership in the Association or which were excluded, as well as their legal successors, have no longer any right in regard to the assets of the Association and they can in no circumstance request any reimbursement of any kind.
- (10) In addition to the provisions of Article 8 (9) above, starting with the date on which it becomes affiliated member, it shall be subject to the annual membership fee in force at that time. Failure to pay the annual fee up to the 30-day deadline set by the payment document leads to the payment of penalties under the form of the legal interest penalty in force at that time, calculated until the date of loss of affiliated membership.
- (11) After the fee payment deadline has passed, OSMR will notify the defaulting member via a notification delay, which will request explanations of this delay and payment within maximum 30 days of the due amount.
- (12) If, after 45 days from the receipt of the notification delay by the respective affiliated member, it fails to comply and fails to pay in full the due amount and the accumulated penalties, it shall be annulled as an affiliated member of OSMR, OSMR being entitled to take the necessary steps to block any rights of the affiliated member related to the National Medicines Verification System and to inform the National Competent Authorities in Romania and EMVO of all these steps taken and of the affiliated member that has been subject to these actions in order for each of them to apply, on their part, the necessary measures.

Article 10. Membership Fees

- (1) Under the reservation of the qualification according to the following paragraph, Member with Full Rights representing one sector shall pay a flat membership fee, as established by the General Meeting on the recommendation of the Management Board, in order to contribute to the costs with the organization and management of OSMR.
- (2) The General Meeting shall establish the annual membership fee for Affiliated Members, on the recommendation of the Management Board.
- (3) Any payment shall be performed within a term of maximum 60 days as of the payment request. The infringement of the obligation to fully pay the annual membership fee on term shall result in the suspension of the voting rights of the Members with Full Powers, until the membership fee is fully paid.

CHAPTER III. SESSION OF THE GENERAL MEETING

Article 11. Structure – Powers

- (1) The General Meeting is made up of all Members with Full Powers.
- (2) Affiliated Members and the representatives of national competent authorities may participate in the sessions of the General Meeting, as observers.
- (3) The Management Board may invite and accept also other external observers at the session of the General Meeting.
- (4) The General Meeting has full powers to establish the general policies, the objectives, methods and actions necessary to fulfil the scope of ORVM.
- (5) The General Meeting shall determine what decisions may be delegated to the Management Board, save those that are subject to the veto right according to Article 14 (c).
- (6) The General Meeting shall revise on an annual basis, as an item on the agenda, based on the report of the Management Board, the compatibility with the structure of EMVO and the resources available to accomplish the objectives.
- (7) The decisions of the General Meeting shall include:
 - (a) the determination of the general strategy and objectives of the Association;
 - (b) the issuance of policies and directions to act in order to fulfil the object of the Association;
 - (c) the approval of the income and expense budget, as well as of the balance sheet;
 - (d) the approval of the activity reports of the Management Board;
 - (e) the approval of the annual budget (inclusively annual membership fees) and annual accounts;
 - (f) the amendment of the Bylaws and of the Articles of Incorporation;
 - (g) the appointment and revocation of the President, Vice-president, Treasurer, Censor, Executive Director and, as the case may be, the General Manager, on the proposal of the Management Board, as well as the determination of their duties;
 - (h) it decides upon the setting up of branches and subsidiaries;
 - (i) the admission of new members and the withdrawal of the membership due to the reasons and in accordance with the procedure provided in articles 6, 8 and 9;
 - (j) the determination of the term and methods of dissolution and winding up OSMR, in terms of the law and it concurrently establishes the destination of the assets remaining after winding up;
 - (k) decisions in regard to the incorporation of trading companies;
 - (l) decisions on the setting up of committees and commissions, determines the attributions, prerogatives and operation method thereof, chooses and revokes their members and establishes the term of their mandate;

- (m) analyzes challenges filed by the entitled persons (Members with Full Powers) against the resolutions/awards/decisions adopted the above committees and commissions;
- (n) adopts, modifies and decides upon the termination of the effects of any codes of conduct, regulations and other internal acts, which are mandatory for all current and future members of the Association, with the possibility of delegating an of such attributions to the Management Board by the decision of the General Meeting;
- (o) decides upon the application of the temporary sanction of the membership in the Association, in case of infringing the adopted codes of conduct/regulations/other internal acts of mandatory nature;
- (p) decides in any matter, field concerning the operation of the Association and decides upon any other measures, within the limits of the law, for the operation of the Association in view of fulfilling its scope.

Article 12. Meetings – Summons

- (1) The General Meeting shall convene in ordinary sessions once a year.
- (2) Extraordinary General Meetings may be summoned on the request of the Members with Full Powers representing at least two thirds from the sectors with voting rights.
- (3) As an alternative to Extraordinary General Meetings, Members with Full Powers may unanimously adopt written resolutions according to Article 14 (b).
- (4) The summons of the sessions of the General Meeting shall be performed by the Management Board, on its initiative or on the written proposal of at least 1/3 (one third) of the Members with Full Powers.
- (5) Sessions shall be held at the registered office of the Association or in any other venue indicated in the summons.
- (6) Sessions shall be chaired by the President of the Management Board or, in his/her absence, by the Vice-president or, in his/her absence, by the member with the longest seniority in position, who is attending.
- (7) The summons shall comprise the agenda, the date, time and venue of the meeting.
- (8) The summons shall be remitted by registered letter with confirmation delivery, e-mail, fax or any other means of written communication ensuring the arrival of the text at the addressee, at least 10 (ten) days before the meeting, save emergency cases that shall be established in writing by the President, a situation in which the summoning term shall be reduced to 3 (three) days.
- (9) The second summons of the General Meeting shall be performed at an interval of 7 (seven) days as of the date of the first summons.
- (10) If all Members with Full Powers are attending or represented at the session, the session of the General Meeting shall be deemed legally convened and it shall be no longer necessary to prove the summoning.

Article 13. Voting Right – Representation

- (1) Each Member with Full Rights shall be entitled to one vote in the General Meeting. If the vote is not directly exerted by the member's appointed representative, he/she shall be entitled to grant a special representation mandate to another person that shall be lodged in written form at the latest before the beginning of the concerned session.
- (2) The vote in the General Assembly Meetings and/or in the meetings of the Management Board can also be done by correspondence: fax, sent to OSMR, e-mail sent to the General Manager and/or the

secretariat and/or to the legal counsellor of OSMR, until 24:00 hrs – Romanian time from the day of the respective meeting. If a member who has expressed his vote by correspondence is personally attending the meeting or has a representative at the meeting, then the vote expressed by correspondence is cancelled, thus only the vote expressed in person or by a representative being considered.

Article 14. Deliberations

(1) The General Assembly Meeting may validly decide only in regard to: (i) issues included in the agenda, or (ii) issues that are not included on the agenda, provided all Members with Full Powers should be attending and unanimously vote in regard to such matter. For such purpose, unanimity supposes that not even one Member with Full Rights opposes.

a) Quorum

(2) The General Meeting may deliberate and validly take decisions if a majority of two thirds from the Members with Full Powers is attending or represented by written power of attorney for that session.

b) Majorities

(3) Decisions of the General Meeting shall be adopted with at least two thirds from the votes of the Members with Full Powers, unless otherwise provided, or unless any of the Members with Full Powers exerts its veto right in the below circumstances.

(4) Members with Full Powers may unanimously adopt written resolutions in regard to all issues included in the powers of the General Meeting. Resolutions adopted according to this procedure shall be remitted to each Affiliated Member within a term of 10 business days as of the adoption thereof.

c) Veto Right

(5) Each Member with Full Rights shall have the following veto rights in regard to the adoption of decisions of the General Meeting, after consultation and debates, provided the exertion of such rights should lead to a result according to the applicable laws:

(a) Amendments of contractual conventions with IT service providers, who infringe the EMVO Requirements (without infringing the provisions of the Directive or of the Delegated Acts), inclusively modifications of the principles in regard to the access to data and management;

(b) Modifications of the principles agreed in regard to the method of assigning the annual costs serving as a guide to invoice Holders of Production and/or Marketing Authorizations, for the use of the System, as provided in the EMVO Requirements;

(c) The increase of the OSMR membership fees by more than 15% versus the previous year;

Article 15. Protocol of the Session of the General Meeting

(1) Resolutions of the session of the General Meeting should be recorded in a protocol.

- (2) The Protocol shall be signed by the President and the session secretary and it shall be officially approved at the following session of the General Meeting.
- (3) The Protocol – except the one that has to be signed in authentic form in front of the notary – and its appendixes are kept in a special registry, at the headquarters of the Association or in secured electronic form, guaranteeing the durability, legibility, integrity and reproduction.
- (4) Members may consult the Protocol at the registered office or may receive a copy.
- (5) Unless the law or the Management Board provides otherwise, copies or excerpts of the Protocol may be signed by the President of the Management Board or the Vice-president.

CHAPTER IV. MANAGEMENT

Article 16. Management Board

- (1) Each Member with Full Rights shall appoint one representative in the Management Board.
- (2) The mandate of the members of the Management Board is of two years.
- (3) The mandate can be renewed in for successive periods of two years and it is not remunerated. If a legal entity is appointed as a Manager, it should appoint an individual representative, who shall exert the mandate of a Manager of OSMR.
- (4) Managers, in the light of their position, shall not gain any personal obligation and they are liable only towards the Association for the fulfilment of the mandate. Managers have the attribution of managing the joint interests of the members.

Article 17. Termination of the Mandate – Vacant Position

- (1) The mandate of a Representative in the Management Board shall be terminated by:
 - (a) Voluntary resignation, with a notice of thirty days remitted to the Management Board;
 - (b) Expiry of the mandate term;
 - (c) Decease;
 - (d) Termination of the contractual or labour relation between the Representative and the Member with Full Rights;
 - (e) Revocation before the expiry of the mandate, by the General Meeting appointing it;
- (2) If the mandate of a representative becomes vacant, the concerned Member with Full Rights is under the obligation to replace it within maximum 60 days.
- (3) The newly-appointed representative shall continue the mandate of the prior Manager, throughout the term reaming from the latter's mandate.

Article 18. Powers of the Management Board – Delegation – Current management of the company

- (1) The Management Board shall ensure itself that OSMR is operating in accordance with the applicable laws and the effective Bylaws.

- (2) The Management Board is made up of an odd number of members, from among whom is selected one President and one Vice-president.
- (3) At the time of setting up the Association, the members of the Management Board are:
 - (a) one President;
 - (b) one Vice-president;
 - (c) three Members.
- (4) The Management Board shall have full powers, except those reserved to the General Meeting, to implement the general policies, objectives, procedures, methods and actions of OSMR, which shall include the following:
 - (a) To ensure itself that the protocols of all meetings of the Management Board are kept and remit, on request, the decisions to all members;
 - (b) To prepare the budget and take all measures necessary in order to ensure the proper financial management of OSMR;
 - (c) To present to the General Meeting the report for the activity on the prior period, the execution of the income and expense budget, the balance sheet, the draft of the income and expense budget and the draft of the Association's programs;
 - (d) Prepares and summons ordinary and extraordinary sessions of the General Meeting and attends to the proper development thereof;
 - (e) Draws up the draft of the annual activity plan;
 - (f) To make recommendations to the General Meeting in regard to the membership fees charged from the affiliated members of OSMR for the use of the European Central System by the National Systems;
 - (g) To make recommendations to the General Meeting in regard to the assignment of the membership fees charged from the Holders of Production and/or Marketing Authorizations for the use of the National Systems. For the avoidance of any doubt, if the Holder of the Production Authorization and the Holder of the Marketing Authorization are not one and the same legal entity, the entity liable for the marketing of the product shall be liable for the payment of the services to OSMR;
 - (h) To delegate in writing and on own liability, the daily management of the Organization to a Manger ("Executive Manager"), or to a third party not having the capacity of a Manager ("Executive Manager"), with the approval of the General Meeting to appoint such a person;
 - (i) To delegate in writing and on own liability the part of its powers to one or several Managers of OSMR or to outsource well-defined services to third parties;
 - (j) To propose, as deemed necessary, the internal regulations compatible with the Bylaws, specifying the provisions of the Bylaws and establishing practical methods to ensure the proper operation and funding of OSMR;
 - (k) To supervise the implementation and monitor on a permanent basis performance issues of NMVS, the management of incidents, operational modifications, the management of the configuration and the security of the access to data and report about each of such issues to the General Meeting. Such tasks shall be executed in cooperation with EMVO, as the case may be, if NMVS decided to subject these issues to the technical verification by EMVO.
 - (l) To propose policies to the General Meeting in regard to the implementation and development of NMVS.

- (m) To perform written and thoroughly grounded recommendations to the General Meeting in regard to the acceptance of new members and terminating the membership, in the cases it deems such necessary.
- (n) Concludes legal deeds on behalf of and for the Association;
- (o) Decides in regard to moving the registered office of the Association;
- (p) Represents the Association in relations with third parties, with courts of laws and other organisations,
- (q) Facilitates the participation in reunions, symposia, conferences, congresses and other forms of national and international manifestations focused on theoretic and practical issues regarding the production, promotion and distribution of medicines,
- (r) Decides in regard to any other management issues related to the proper development of the Association's activity,
- (s) Fulfils any other attributions provides in the Bylaws or established by the General Meeting.
- (t) The Management Board has the power to set up and dissolve any commissions and determine the structure, remuneration and working method thereof.

(5) Documents in regard to the appointment and revocation/resignation of Mangers and, as the case may be, of persons authorized to represent the Association, are registered and published in accordance with the applicable legal provisions, in the Register of Associations and Foundations, attached to the Registrar's Office of the Court of Law, where the registered office of OSMR is located.

Article 19. Meetings of the Management Board

- (1) OSMR shall be managed by a Management Board that shall convene at least three times a year.
- (2) The Management Board shall convene in extraordinary session, if at least two of the members request such a meeting.
- (3) The summons shall comprise the agenda, date, time and venue of the meeting. The summons shall be remitted by registered letter with delivery confirmation, e-mail, fax or any other written means of communication ensuring the arrival of the text to the addressee, at least 5 (five) days before the date of the session, except urgent cases that should be justified, when the summoning period is reduced to 3 (three) days. Meetings are held at the registered office of OSMR or at another venue indicated in the summons.
- (4) If all Representatives are attending or are represented at the session, the meeting of the Management Board shall be deemed legally convened and no more proof of summoning the members shall be necessary legal.

Article 20. Deliberations of the Management Board

- (1) The Management Board shall validly deliberate in the attendance of 2/3 (two thirds) from the number of its members – represented sectors, and adopts decision with (i) simple majority, if the quorum is fully convened at the meeting of the Management Board; or (ii) absolute majority, if only the minimum quorum is convened (2/3) at the meeting of the Management Board.
- (2) The following actions are subject to the unanimous approval as long as there are 2/3 of the Members with Full Powers or the approval of two thirds from the Managers, if the Members with Full Powers represent at least three sectors, for:

- (a) The approval of expenses exceeding the amount of 10,000 € (except payments owed for the maintenance of employees and updating of NMVS),
 - (b) The amendment of the terms from the contract concluded with the IT provider,
 - (c) The appointment and revocation of the President, Vice-president and/or Censor, if the case may be.
- (3) All the other decisions shall be taken with the simple majority of the Managers attending or duly represented at the meeting of the Management Board.
- (4) The non-exertion of the voting right shall be deemed refraining.
- (5) The meeting of the Management Board may be kept by teleconference or videoconference, provided the resolution adopted at such conference or videoconference should be subsequently transcribed in protocols that are remitted to each Representative, in order to be fulfilled, if the case may be.

Article 21. Session Protocol of the Management Board

- (1) All resolutions of the Management Board should be recorded in protocols.
- (2) Protocols shall be signed by the President and two Members and are officially approved at the next meeting.
- (3) The Protocol and its appendixes shall be kept with a special registry at the headquarters of the Association, in original, or in secured electronic format with the guarantee of the durability, legibility, integrity and reproduction.
- (4) Excerpts of the protocol can be remitted to third parties justifying an interest. Unless the law or the Management Board provides otherwise, copies or excerpts of the protocols should be signed by the President of the Management Board or by the Vice-president.

Article 22. Internal Regulations

- (1) The General Meeting may issue internal regulations in accordance with these Bylaws, providing methods of ensuring the proper operation and funding of the Association.
- (2) The amendment of such internal regulations is an exclusive prerogative of the General Meeting that shall decide in this view, on the proposal of the Management Board.
- (3) Internal Regulations shall provide the liability of the Management Board to establish an annual budget.
- (4) The Management Board shall reassess each year the applicable internal regulations and perform the amendments that shall be considered necessary or useful.

Article 23. Representatives

- (1) OSMR shall be represented by the President, Vice-president or the Censor, in particular cases.
- (2) An Executive Manager or a General Manager may be additionally appointed.
- (3) The President and Vice-president shall assure that the Management Board adequately fulfils its task of drafting and implementing the strategy of the Association.
- (4) They shall chair the meetings of the Management Board and of the General Meeting and they shall fulfil the policies and instructions of such management bodies.
- (5) The main attributions of the President and, in his/her absence, of the Vice-president, shall include:
- (a) To summon all meetings of the General Meeting and Management Board,

- (b) To execute the policies decided by the Management Board and propose corresponding plans to the Management Board, as well as to manage their execution,
 - (c) To establish and maintain the adequate communication with all members,
 - (d) To cooperate with the representatives of OSMR in order to ensure the operation and management of the IT system,
 - (e) To ensure the adequate communication with the NMVS users,
 - (f) To represent OSMR and its members in front of third parties, inclusively governmental authorities.
- (6) The Executive Manager or General Manager, as the case may be, shall be liable of the daily management of OSMR.
- (7) This includes:
- (i) all issues deriving from the usual activity of OSMR or
 - (ii) issues that have to be treated in a quick manner, so as not to interrupt the daily operations of OSMR.
- (8) The Management Board may specify the issues related to the current activity of OSMR.
- (9) The Executive Manager or General Manager, as the case may be, shall supply to the Management Board, in due time, all information necessary to it, in order to fulfil its attributions and it shall be held liable by the Board for the failure to fulfil his/her attributions.
- (10) Without infringing the general powers of the Management Board as a college body, the Association is duly represented in the legal procedures and towards third parties, inclusively, but not limited to the public servants (such as bank clerks), by:
- (a) an ad-hoc representative, appointed by special power of attorney by the Management Board;
 - (b) the President of the Management Board, acting individually;
 - (c) the Vice-president, acting individually;
 - (d) the Executive Manager or General Manager, as the case may be, acting individually, within the limits of the delegated management powers.
- (11) No other justification or decision of the Management Board shall be necessary for such purpose.

CHAPTER V. TAX YEAR – ANNUAL ACCOUNTS – BUDGET – AUDIT

Article 24. Tax year – Annual Accounts

- (1) The tax year shall start on 1 January and ends on 31 December of each year.
- (2) The Management Board shall prepare each year the annual accounts of the tax year that ended, in accordance with the applicable laws, as well as the budget for the following tax year. Such are subject to the approval of the General Meeting on its first meeting.
- (3) The books shall be kept in accordance with the legal provisions in the field and the applicable regulations.

Article 25. Audit – Statutory Audit

- (1) If necessary, according to the applicable laws, or on request of every Member with Full Rights shall be performed an annual audit of the financial statements of the Association, of the annual accounts and the compliance with the applicable laws and these Bylaws, of the operations included in the annual accounts, by an auditor appointed by the General Meeting.
- (2) Auditors are appointed for a 3-year period, which may be renewed.

- (3) Their remuneration can be modified only with the approval of the parties and it shall be paid by OSMR.

CHAPTER VI. AMENDMENTS OF THE BYLAWS – DISSOLUTION

Article 26. Special Terms for the Amendment of the Bylaws

- (1) The Bylaws may be amended at any time by the decision of the General Meeting.
- (2) The General Meeting cannot duly decide upon the amendment of the Bylaws, unless this issue is included in the summons and provided at least two thirds of the Members with Full Powers are attending or represented.
- (3) If this quorum is not fulfilled, a second meeting shall be summoned, with the same agenda and in the same terms as the first meeting, which shall validly deliberate whether at least two thirds of the Members with Full Powers are attending or represented.
- (4) The second meeting cannot be held earlier than seven days or later than six weeks as of the first meeting.
- (5) Any amendment of the scope of the Association, as well as of the activities that it carries out in view of accomplishing the scope, shall be immediately effective, unless the national law provides otherwise.

Article 27. Dissolution – Winding up – Distributions of the Goods

- (1) Without infringing the provisions of Government Ordinance 26/2006, the Association can be dissolved any time by the decision of the General Meeting, adopted with a majority of two thirds from the votes of the sectors represented by the Members with Full Powers attending the meeting or represented at it.
- (2) In case of dissolving the Association due to any reason, its winding up such shall be entrusted to one or more liquidators, chosen by the decision of the General Meeting, or in its absence, by court decision.
- (3) In case of voluntary or legal dissolution, due to any reason and at any time, the liquidator shall pay the debts of the associations with the goods of the Associations and the assignment of the goods shall be determined by the General Meeting or by the liquidators.
- (4) The goods shall be remitted to a legal entity of private law or of public law with identical or similar scope.

CHAPTER VII. REVENUES OF OSMR

Article 28. Revenues of the Association

- (1) The revenues of the Association may derive from:
 - (a) the membership fee;
 - (b) interests and dividends resulting from the placement of available amounts, in legal terms;
 - (c) dividends of the companies incorporated by the Association;
 - (d) donations, sponsorships, legacies;
 - (e) resources obtained from the State budget or the local budgets;

- (f) other revenues provided by the law.
- (3) The annual membership fee of the members of the Association shall be established at the first annual meeting after incorporation. The amount of the annual membership fee, the payment method and term thereof may be reviewed on an annual basis by the General Meeting based on the proposal of the Management Board.
- (4) The Association may carry out any other economic activity, if such is of an accessory nature and is related to the main scope of the Association.
- (5) The revenues of the Association shall be used only to cover the own expenses related to the operation thereof, or for any other action compliant with the scope of the Association, previously approved by the General Meeting or by competence delegation, by the Management Board.

CHAPTER VIII. GENERAL PROVISIONS

Article 29. Resolutions of disputes – Applicable law and jurisdiction – Legal references

- (1) OSMR may use any and all actions in front of the competent courts of law in order to request amounts of money owed by the users or members.
- (2) The provisions of these Bylaws are drafted according to the requirements of Government Ordinance no. 26/2000 and may be amended by decision of the General Meeting, with the vote of 2/3 (two thirds) from the number of the Association members.
- (3) The working language at the Association is the Romanian language.
- (4) These Bylaws is signed today, the certification date, 5 (five) counterparts, all original and having the same validity, of which one counterpart was released to OSMR, 3 (three) counterparts shall be lodged with the Court of Law of District 3 and one was kept with the archive of the lawyer certifying such.

FOUNDING MEMBERS

By representative, Laurentiu Teodor MIHAI, General Manager

The undersigned, Carmen-Maria Mateescu, sworn interpreter and translator for the English and German languages by virtue of license no. 4678 from 18 June 2001 issued by the Ministry of Justice from Romania, certify the accuracy of the translation performed from the Romanian language into the English language, that the presented text was fully translated with no omissions and that by the translation was not distorted the content and meaning of the deed.

SWORN TRANSLATOR AND INTERPRETER