

**CHARTER**  
**OF THE NATIONAL MEDICINES AUTHENTICITY VERIFICATION ORGANISATION FOUNDATION**

**PREAMBLE**

The basis for establishment of the National Medicines Authenticity Verification Organisation is comprised in the provisions of Directive 2011/62/EC of the European Parliament and of the Council amending Directive 2001/83/EC of the European Parliament and of the Council 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 along with the subsequent Commission Delegated Regulation (EU) 2016/161 of 2 October 2015.

Implementation of the legal acts specified above proceeds by way of duties imposed upon, and rights accorded to, organisations assembling manufacturers of medicinal products with security features ensuring their authenticity by way of this Charter. These include duties as regards:

- Selection of a repositories system in Poland which stores, inter alia, the information on the legitimate unique identifiers of a medicinal product and can be queried for the purposes of verifying the authenticity of a unique identifier;
- Selection of the entity which will be supplying this system;
- Approval of the budget of the National Medicines Authenticity Verification Organisation;
- Approval of means for calculating fees for use of this system and the applicable rates.

**CHAPTER I GENERAL PROVISIONS**

**§ 1.**

The National Medicines Authenticity Verification Organisation, hereinafter referred to as “the Foundation”, is established by:

1. The Employers' Association of Innovative Pharmaceutical Companies INFARMA with its registered seat in Warsaw, entered in the register of business enterprises and in the register of associations, other civic and professional organisations, foundations and independent public health care entities maintained by the District Court for the capital city of Warsaw in Warsaw, Division XIII – Commercial of the National Court Register under no. KRS 0000259970;
2. The Polish Union of Pharmaceutical Industry Employers with its registered seat in Warsaw, entered in the register of associations, other civic and professional organisations, foundations and independent public health care entities maintained by the District Court for the capital city of Warsaw in Warsaw, Division XIII – Commercial of the National Court Register under no. KRS 0000131235;
3. The Association of Parallel Importers of Medicinal Products with its registered seat in Warsaw, entered in the register of associations, other civic and professional organisations, foundations and

independent public health care entities maintained by the District Court for the capital city of Warsaw in Warsaw, Division XIII – Commercial of the National Court Register under no. KRS 0000263775;

hereinafter referred to as “the Founders”, established by way of the notarial deed drawn up on 2 June 2017 by Mr Grzegorz Rogala, notary public with Kancelaria Notarialna w Warszawie at ul. Rondo ONZ 1 (rep. no. A-6741/2017), and it pursues its operations on the basis of the legislative Act of 6 April 1984 regarding foundations and of this Charter.

#### **§ 2.**

1. The seat of the Foundation shall be in the capital city of Warsaw.
2. The Foundation pursues its operations in Poland and abroad.
3. The Foundation is established for an indefinite period of time.

#### **§ 3.**

The minister competent to exercise supervision over the Foundation shall be the minister competent for health matters.

#### **§ 4.**

1. The Foundation is a non-profit organisation.
2. The Foundation may establish branches, representative units, offices and other organisational units pursuing its core objectives, as defined herein.

### **CHAPTER II OPERATIONS OF THE FOUNDATION – OBJECTIVES, PRINCIPLES**

#### **§ 5.**

1. The Foundation is established for the sole purpose of implementing the provisions of Directive 2011/62/EC and of the Commission Delegated Regulation (EU) 2016/161 (hereinafter jointly referred to as “the Basic Acts”), i.e. for the purpose of setting up and managing a repositories system in Poland which stores, inter alia, the information on the legitimate unique identifiers of a medicinal product and can be queried for the purposes of verifying the authenticity of a unique identifier (hereinafter referred to as “the System”). The System shall be an element of the comprehensive medicines verification system created in accordance with the Basic Acts.
2. The Foundation shall pursue its objectives in cooperation with the European Medicines Verification with its seat in Brussels, hereinafter referred to as “EMVO”.
3. The functionalities of the system for protecting against falsified medicinal products in Poland shall not depart beyond the scope described in Directive 2011/62/EC and in the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015.
4. Establishment of the Foundation shall remain without prejudice to ownership and contents of the data processed within the system for protecting against falsified medicinal products in Poland, which also ensures security and confidentiality of the data processed therein.

5. Supervision over the System in accordance with the Basic Acts shall be exercised by the minister competent for health matters.

#### **§ 6.**

The Foundation shall pursue its objectives employing means commensurate to these objectives' nature by:

1. Defining criteria for selection and structuring of the System;
2. Defining technical standards for the System so as to guarantee overall quality and stability of operation;
3. Preparation and activation of the System, supervision over its operations;
4. Safeguarding and development of intellectual property of the Foundation pertaining to management and maintenance of the System;
5. Establishment of appropriate financing and financial security structures enabling due maintenance and development of the System in cooperation with its users, i.e. with manufacturers of medicinal products covered by the duty of monitoring authenticity and/or their representatives (hereinafter referred to as the "System Users");
6. Cooperation with EMVO and with the National Medicines Verification Organisations established pursuant to the Basic Acts in other European countries;
7. Implementation of innovative solutions within the System so as to bring the System in line with requirements imposed by EMVO;
8. Pursuit of non-profit information, advisory, and educational activities relating to management of the System and propagating its essence, features, and aims.

#### **§ 7.**

Within the scope necessary for pursuit of its core objectives, as defined herein, the Foundation may hire employees pursuant to employment contracts as well as entrust specific tasks or actions on the basis of other legal relationships.

### **CHAPTER III ASSETS OF THE FOUNDATION**

#### **§ 8.**

The initial assets of the Foundation shall be comprised in the Foundation's endowment of PLN 215,000 (two hundred fifteen thousand zloty) provided in its entirety by the Founders as follows:

1. The Employers' Association of Innovative Pharmaceutical Companies INFARMA – PLN 100,000 (one hundred thousand zloty);
2. The Polish Union of Pharmaceutical Industry Employers – PLN 100,000 (one hundred thousand zloty);
3. The Association of Parallel Importers of Medicinal Products – PLN 15,000 (fifteen thousand zloty).

#### **§ 9.**

The Foundation shall be liable for its liabilities and obligations up to the full value of its assets.

**§ 10.**

1. The sources of financing for pursuit of the Foundation's objectives and for covering its operating expenses shall be comprised in:
  - a) The endowment;
  - b) Revenue from non-profit core operations;
  - c) Loans and/or credit facilities;
  - d) Bequests, inheritances, gifts, donations and subsidies from domestic and foreign persons and entities;
  - e) Benefits accruing from chattels, real estate and from other material rights;
  - f) Revenue from collections;
  - g) Interest from bank deposits and securities.
2. The Founders shall be obligated to ensure sufficient financing for day-to-day operations of the Foundation, as provided for in the Foundation's budget subject to approval by the Foundation Council in accordance with § 19.2 below.
3. The Founders shall provide the financing referred to in section 2 above in the following proportions:
  - a) The Employers' Association of Innovative Pharmaceutical Companies INFARMA shall provide 60%;
  - b) The Polish Union of Pharmaceutical Industry Employers shall provide 35%;
  - c) The Association of Parallel Importers of Medicinal Products shall provide 5%.

**§ 11.**

Any surplus of revenues over costs shall be devoted by the Foundation to its core objectives, as defined herein.

**§ 12.**

In the event that the Foundation becomes eligible for an inheritance, the Board shall make a declaration accepting such inheritance with the benefit of inventory (*z dobrodziejstwem inwentarza*).

**CHAPTER IV GOVERNING BODIES OF THE FOUNDATION**

**§ 13.**

The governing bodies of the Foundation shall comprise:

1. The Foundation Council; 2. The Board.

**§ 14.**

1. The governing bodies of the Foundation shall adopt decisions in the form of resolutions. Persons entitled to vote and to participate in sessions of the Foundation's governing bodies may exercise

their rights by proxy. Any powers of attorney should be granted in writing, failing which the given proxy may not be allowed to participate in the session or to vote.

2. Resolutions of the Foundation's governing bodies shall be adopted in an open ballot.
3. Unless this Charter or applicable laws provide otherwise, resolutions of the Foundation's governing bodies shall be adopted by an ordinary majority, meaning more votes cast in favour of a resolution than against that resolution.
4. Resolutions of the Foundation's governing bodies may be adopted even if no session of the Foundation Council or the Board has been formally called, provided that all the parties entitled to vote on such resolution are represented and that none of those present has objected to holding such session of the Foundation Council or of the Board or to the inclusion of specific items on its agenda.
5. Resolutions of the Foundation's governing bodies may also be adopted without holding a session of the Foundation Council or the Board if all the parties entitled to vote on such resolution have agreed in writing to the decision to be thus adopted or to the holding of a written ballot.
6. Participation in sessions of the Foundation's governing bodies is also possible via direct long-distance communications technologies.

### **The Foundation Council**

#### **§ 15.**

1. The Foundation Council shall exercise supervision over day-to-day operations of the Board.
2. For purposes of performance of its duties, Foundation Council may, either personally or through designated persons, examine all Foundation documents, request reports and clarifications from the Board and from Foundation employees, and audit the Foundation's assets.

#### **§ 16.**

1. The Foundation Council shall be composed of 5 (five) members, with each one of the Founders appointing 1 (one) member, with 1 (one) member appointed by the Polish Pharmaceutical Chamber and with 1 (one) member appointed by Association of Polish Pharmaceutical Wholesalers Employers, with its registered seat in Warsaw, entered in the register of business enterprises and in the register of associations, other civic and professional organisations, foundations and independent public health care entities maintained by the District Court for the capital city of Warsaw in Warsaw, Division XIII – Commercial of the National Court Register under no. KRS 0000224375 (hereinafter referred to as "ZPHF")
2. With the exception of the first composition of the Foundation Council, whose members shall be appointed in the Charter, the right to appoint and to remove Foundation Council members vested in the Founders, in the Polish Pharmaceutical Chamber and ZPHF discussed in section 1 above shall be exercised by way of submission to the Foundation Board of a declaration concerning appointment or removal of a Foundation Council member. Any appointment or removal shall be effective as of delivery of the written declaration by the Founder or by the Polish Pharmaceutical Chamber or by ZPHF to the Foundation's seat.

3. The following persons shall be barred from sitting on the Foundation Council: members of the Foundation Board, a liquidator, a manager of any branch, representative unit, office, or other organisational unit or facility, the Foundation's chief financial officer, an attorney or advocate retained by the Foundation, and relatives (consanguineous as well as other relatives) of such persons and persons subordinated to them by virtue of an employment relationship.
4. Foundation Council members shall be appointed for an indefinite term.
5. The mandate of a Foundation Council member shall expire as of her/his removal by the appointing Founder, by the Polish Pharmaceutical Chamber or by ZPHF, her/his resignation or her/his death.
6. Every Foundation Council member may resign from the Foundation Council by serving written notice to that effect, subject to a 30-day period of notice effective at the end of the calendar month.

**§ 17.**

Service as a Foundation Council member shall be provided without remuneration. Any and all expenses associated with the work of a Foundation Council member shall be covered by the entity which appointed that member in accordance with § 16.1 above.

**§ 18.**

1. Work of the Foundation Council shall be managed by the Foundation Council Chairman. The Chairman shall call Foundation Council sessions and define their agenda.
2. The position of Chairman shall be held for a term of 1 (one) calendar year, on a rotational basis, by successive members of the Foundation Council. The first Chairman shall be the Foundation Council Chairman member appointed by the Employers' Association of Innovative Pharmaceutical Companies INFARMA, and then – in this order of sequence – the member appointed by the Polish Union of Pharmaceutical Industry Employers, by the Association of Parallel Importers of Medicinal Products, by the Polish Pharmaceutical Chamber and by ZPHF.
3. The Foundation Council Chairman shall be empowered to communicate positions of the Foundation Council to third parties.
4. The Foundation Council shall meet during sessions called as warranted by circumstances, but not less frequently than one every 3 (three) months. Foundation Council sessions shall be documented in minutes.
5. Every Foundation Council member shall have one vote on the Council.
6. The ambit of the Foundation Council shall encompass any and all matters not reserved for other governing bodies of the Foundation by this Charter or by applicable laws.
7. Associated Organisations may participate in work of the Foundation Council in an advisory capacity in accordance with § 29 below.

**§ 19.**

The exclusive purview of the Foundation Council shall include:

1. Approval of the System supplier selected by the Board for realisation of the objectives discussed in § 5.1 above;

2. Approval of the Foundation's budget presented by the Board;
3. Consideration and approval of the Board's reports on operations of the Foundation and of the Foundation's financial report for the previous financial year;
4. Adoption of resolutions concerning commencement and conclusion of the Foundation's liquidation;
5. Approval for effectuation of disposals, and assumption of liabilities, of a value exceeding PLN 100,000 (one hundred thousand zloty) other than contracts for financing of the System creation costs executed with the System Users;
6. Consideration of applications by prospective Associated Organisations;
7. Granting permission for divestment, encumbrance, or purchase of real estate by the Foundation;
8. Adoption of rules governing operations of the Foundation Council and the Foundation Board;
9. Defining priorities for the Foundation's operations;
10. Acceptance of other reports by the Board;
11. Granting permission for execution, amendment, and termination of contracts between the Foundation and members of its governing bodies;
12. Where requested by the Board, consultations with respect to actions of the Board;
13. Selection of certified auditors for auditing of the financial report;
14. Definition of terms for auditing operation of the System;
15. Appointment and removal of Board members;
16. Day-to-day assessment of the Board's activities;
17. Approval of the terms in office of Board members;
18. Appointment of a plenipotentiary for execution of contracts between Board members and the Foundation and for representation of the Foundation in any disputes with Board members;
19. Convention of working groups and advisory teams, indication of organisations invited to join in their work;
20. Granting permission for defining means for calculating fees for use of the System and the applicable rates (and of any changes thereto);
21. Granting permission for defining non-disclosure rules for data processed in the System (and of any changes thereto);
22. Granting permission for any departures from the terms defined in the Blueprint;
23. Definition of the first version and of changes to the URS (User Requirements Specification);
24. Taking decisions with respect to the System as regards functioning and costs of the information technology infrastructure and the hardware and software for persons empowered or authorised to provide medicinal products to patients in order to enable realisation of objectives, in particular as regards:
  - Identification of individual medicinal product packages with security features;
  - Verification of the authenticity of the unique identifier on such package;
  - Pulling packages from the legal distribution system at the retail level;
25. Amendment of the Foundation's Charter;

26. Adoption of rules defining the terms for contacts and cooperation with Associated Organisations.

**§ 20.**

1. Foundation Council resolutions shall be adopted subject to the following rules:
  - a) Resolutions concerning the matters defined in § 19 items 6, 7, 8, 21, 23, 24, 25, and 26 above shall require unanimity of all the Foundation Council members;
  - b) Resolutions concerning the matters defined in § 19 items 1, 2, 3, 20, and 22 are adopted by an ordinary majority, however unanimity of all members of the Foundation Council appointed by the Founders is required;;
  - c) Resolutions other than those referred to in letter a) and b) above shall be adopted by an ordinary majority.
2. The requirements specified in section 1 letter a) – c) above refer to Foundation Council members in attendance at the session.

**§ 21.**

1. In the event that there arises a situation in which the interests of the Foundation are conflicted with the interests of any Foundation Council member or with the interests of such Council member's spouse, consanguineous relatives and relatives to the second degree, or of persons whose relationship with that Council member may give rise to doubts concerning her/his impartiality, such Foundation Council member should recuse herself/himself from ruling on such matters, and this fact should be noted in the minutes of the Foundation Council session.
2. For purposes of acts in law between the Foundation and a Foundation Council member and of any disputes between the Foundation and a Foundation Council member, the Foundation shall be represented by a plenipotentiary appointed by way of a Foundation resolution.

**The Foundation Board**

**§ 22.**

1. The Board manages operations of the Foundation and represents it vis a vis third parties.
2. The Board shall be responsible for day-to-day administration of the Foundation's operations.
3. The Board shall operate on the basis of the Board regulations resolved upon by the Foundation Council, of this Charter, and of applicable laws.
4. In its operations, the Board shall be guided by considerations of the good of the Foundation and strive towards attainment of the Foundation's objectives, prioritising the interests of the Foundation.

**§ 23.**

1. The Board shall be composed of between 1 (one) and 3 (three) natural persons.



2. With the exception of the first composition of the Board, whose members shall be appointed in the Charter, the right to appoint and to remove Board members is vested in the Foundation Council. The number of Board members shall be defined by the Foundation Council, subject to the reservation that the first composition of the Board shall comprise 1 (one) member, who shall serve as the President of the Board.
3. The Foundation Council shall select a President of the Board and Vice Presidents of the Board from among the Board members.
4. Board membership shall be barred to persons convicted, with no possibility of further ordinary appeal (*wyrok prawomocny*), of a deliberate crime subject to public prosecution or for a fiscal offence.
5. Board members shall be appointed for an indefinite term.
6. The mandate of a Board member shall expire as of her/his removal, her/his resignation or her/his death.

#### **§ 24.**

Authority to incur financial liabilities and to make declarations of intent on behalf of the Foundation shall be vested in the President of the Board acting jointly with 1 (one) other Board member. In the case of a single-person composition of the Board, the Foundation shall be represented by the sole Board member acting on her/his own.

#### **§ 25.**

Service on the Board shall be paid, with the amount of remuneration defined by the Foundation Council by way of a resolution.

#### **§ 26.**

1. Board sessions should be held at least once every month.
2. Board sessions may be held via direct long-distance communications technologies, as provided for in the Board regulations.
3. Board resolutions shall be adopted by an ordinary majority of the Board members' votes.
4. Every Board member shall have 1 (one) vote at a Board session. In the event of a tied vote, the matter shall be decided by the vote of the President.

#### **§ 27.**

The exclusive purview of the Board shall include:

1. Management of the day-to-day affairs of the Foundation;
2. Representation of the Foundation vis a vis third parties;
3. Management of the Foundation's assets;
4. Selection of the System supplier or change of the supplier in performance of the objectives discussed in § 5.1 above;

5. Ensuring administrative support for the Foundation, in particular by supervising operations of the secretariat;
6. Maintaining contacts with the Associated Organisations;
7. Drawing up financial plans and reports, discharge of other reporting duties;
8. Execution of contracts with System Users;
9. Organisation of annual reporting and information meetings for the Associated Organisations;
10. Execution of other contracts on behalf of the Foundation.

#### **§ 28.**

1. In the event that there arises a situation in which the interests of the Foundation are conflicted with the interests of any Board member or with the interests of such Board member's spouse, consanguineous relatives and relatives to the second degree, or of persons whose relationship with that Board member may give rise to doubts concerning her/his impartiality, such Board member should recuse herself/himself from ruling on such matters, and this fact should be noted in the minutes of the Board session.
2. For purposes of acts in law between the Foundation and a Board member and of any disputes between the Foundation and a Board member, the Foundation shall be represented by the Chairman of the Foundation Council or by a plenipotentiary appointed by the Foundation Council on the basis of § 19.18 above.

### **CHAPTER V ASSOCIATED ORGANISATIONS**

#### **§ 29.**

1. All entities duly entitled under Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 may join in the Foundation Council's work on a voluntary basis ("Associated Organisations"). The terms of participation in the Foundation Council's work are defined in sections 2-5 below.
2. The organisations referred to in section 1 shall file an application accompanied by a declaration of intent by their governing body concerning desire to join in the Foundation Council's work (in written form, with a certified date). Such application shall be considered by the Foundation Council.
3. The organisations referred to in section 1 may present their positions on matters being addressed by the Foundation Council. The Foundation Council shall request that Associated Organisations present their positions on the matters referred to in § 19 items 20-22 above.
4. When invited to do so by the Foundation Council, the Associated Organisations may participate in the work of teams and working groups convened by the Foundation Council.
5. An Associated Organisation shall authorise 1 (one) person to work with the teams and groups referred to in section 4.
6. The terms of contacts and cooperation with the organisations referred to in section 1 shall be defined in rules adopted by the Foundation Council.

## **CHAPTER VI AUDITS ACCOUNTANCY REPORTING**

### **§ 30.**

1. The Foundation shall submit to the supervisory authority annual reports on its operations in the previous year.
2. The financial year of the Foundation shall coincide with the calendar year.
3. The first financial year of the Foundation shall end on 31 December 2017.
4. Each Founder may request an independent audit of the System's information technology security and of security of the data contained therein subject to terms defined by the Founder commissioning such audit. § 19.14 above shall not apply to such audit. Such audit may be performed not more frequently than once per calendar year. Such audit shall be performed at the expense of the Founder requesting it by an entity providing such services on a professional basis which guarantees confidentiality and due execution of the audit. The results of any such audit shall be promptly made available to the Foundation Council.

## **CHAPTER VII FINAL PROVISIONS**

### **§ 31.**

1. The Foundation may be liquidated by the Founders upon attainment of its objectives.
2. Such liquidation shall require a unanimous resolution adopted by the Founders.
3. The liquidator of the Foundation shall be appointed by the Foundation Council; where no liquidator has been appointed, this function shall be performed by the President of the Board.
4. Any assets remaining upon the Foundation's liquidation shall be earmarked for an objective of public or economic utility indicated in a resolution of the Foundation Council.

### **§ 32.**

1. The first composition of the Board shall comprise Ms Bogna Cichowska-Duma, President of the Board.
2. The first composition of the Foundation Council shall comprise:
  - Mr Jarosław Oleszczuk as the member appointed by the Employers' Association of Innovative Pharmaceutical Companies INFARMA;
  - Mr Krzysztof Kopeć as the member appointed by the Polish Union of Pharmaceutical Industry Employers;
  - Mr Tomasz Dzitko as the member appointed by the Association of Parallel Importers of Medicinal Products;
  - Ms Elżbieta Piotrowska Rutkowska as the member appointed by the Polish Pharmaceutical Chamber.