

**REGULATIONS DEFINING THE PRINCIPLES OF RELATIONS AND COOPERATION  
WITH ASSOCIATED ORGANISATIONS OF THE POLISH MEDICINES VERIFICATION  
ORGANISATION FOUNDATION  
(REGULATIONS)**

**CHAPTER 1. GENERAL PROVISIONS**

**§ 1.**

These Regulations define the principles of relations and cooperation with Associated Organizations of the National Medicines Verification System Foundation, including:

- 1) the mode of applying for the status of Associated Organization;
- 2) the basic rules for participation of Associated Organizations in the works of the Council;
- 3) the rights and obligations of an Associated Organization and the Council;
- 4) the rules for communication with Associated Organizations;
- 5) matters related to the loss of the status of an Associated Organization.

**§ 2.**

The definitions used in these Regulations shall mean:

- 1) “**Foundation**” — shall mean the National Medicines Verification System Foundation.
- 2) “**Associated Organization**” — shall mean every entity that has been granted the relevant right under the Delegated Regulation and whose application for participation in the works of the Council of the Foundation, submitted pursuant to § 29 of the Statute and § 5 of these Regulations has been approved by the Council.
- 3) “**Council**” — shall mean the Council of the Foundation.
- 4) “**Delegated Regulation**” — shall mean the 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.
- 5) “**Statute**” — shall mean the Statute of the Foundation.
- 6) “**System**” — shall mean a system of databases in Poland that stores information on *inter alia* legal unique medicinal product identifiers and provides the functionality to search for a unique medicinal product identifier in order to verify its authenticity, established in accordance with the provisions of the Directive of the European Parliament and of the Council 2011/62/EU 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, together with the adopted Delegated Regulation.
- 7) “**Participants**” — shall mean the entities participating in the works of the Council of the

Foundation, i.e. the Employers' Union of Innovative Pharmaceutical Companies INFARMA, Polish Union of Employers in Pharmaceutical Industry, the Association of Parallel Importers of Medicinal Products, the Polish Pharmaceutical Chamber and Associated Organizations.

- 8) **“System Users”** — shall mean the manufacturers of medicinal products subject to the obligation of authenticity monitoring, or entities that represent them.
- 9) **“Management Board”** — shall mean the Management Board of the Foundation.

### § 3.

1. The entities to which the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 grants a relevant right shall be entitled to participate in the works of the Foundation after receiving the status of an Associated Organization that enables them to participate in the works of the Council.
2. The procedures for receiving the status of an Associated Organization are defined in the Statute (§ 29) and in these Regulations.

## **CHAPTER 2. BASIC RULES OF COOPERATION BETWEEN THE FOUNDATION AND ASSOCIATED ORGANIZATIONS**

### § 4.

1. Participation of Associated Organizations in the works of the Council is governed by the following basic principles that must be followed by all Associated Organizations:
  - 1) the principle of voluntariness — an organization seeking the status of an Associated Organization shall make the decision to participate in the works of the Council voluntarily. The Associated Organization may at any time waive its status of an Associated Organization. Participation in the works of the Foundation is not required to use the System.
  - 2) the principle of legality — Associated Organizations are obligated to act within the limits set by the applicable laws, including the regulations of the Delegated Regulation.
  - 3) the principle of confidentiality — Associated Organizations shall be obligated to maintain strict confidentiality of any information obtained during and in relation to participation in the works of the Council and to use them solely for the purpose for which they have been shared. Detailed regulations regarding protection of confidential information are defined in Appendix No 1 to these Regulations.
  - 4) the principle of Partnership — the Associated Organizations participating in the works of the Council shall respect other Participants;
  - 5) the principle of equality — subject to § 6 of the Regulations on fees, all Associated Organizations shall have the same rights and obligations. None of the Associated Organizations shall be favoured over others.
  - 6) the principle of fair competition — information obtained by Associated Organizations as part

of their participation in the works of the Foundation must not be used directly or indirectly to gain unfair market advantage, in particular over the System Users or entities that enter data into the System (and in particular wholesalers and persons authorized or qualified to deliver medications to patients).

2. The Council shall be obligated to observe the basic principles as defined in section 1 in relation to all Associated Organizations.

### **CHAPTER 3. OBTAINING THE STATUS OF AN ASSOCIATED ORGANIZATION**

#### **§ 5.**

1. An Organization intending to participate in the works of the Council in the character of an Associated Organization shall apply by submitting a form, the template of which is provided in Appendix No 2 to these Regulations, along with a statement of will of the statute bodies regarding participation in the works of the Council. The documents shall be in writing, marked by a certified date.
2. The application shall include:
  - 1) The Statute or other relevant document indicating the object of the organization's activities;
  - 2) The current (i.e. issued within the last three months) excerpt from a relevant register to which the organization has been entered (e.g. National Court Register);
  - 3) A justification confirming the organization's authorization to participate in the works of the Council, in accordance with the applicable law, including this Delegated Regulation;
  - 4) Declaration of familiarity with these Regulations along with an official declaration to:
    - a. observe the basic principles, as referred to in § 4 of the Regulations;
    - b. observe the principles of confidentiality, as defined in Appendix No 1 to these Regulations;
3. The application shall be submitted to the address of the seat of the Foundation. The Management Board shall forward the application to the Council for further processing.
4. If the submitted application is incomplete, the Council shall advise the Management Board to call upon the organization to provide any missing information, indicating the information that is missing.
5. If an organization's application to participate in the works of the Council as an Associated Organization is rejected, the organization may apply for re-examination of its application.
6. The Council shall process the applications as referred to in section 1 and section 5 within 30 days from the date of receiving the complete application.
7. If a given organization is entitled to participate in the works of the Foundation, in accordance with the applicable legal regulations, and has submitted a complete application, the Council cannot refuse the organization the right to participate in the works of the Council as an Associated

Organization.

## **CHAPTER 4. RIGHTS AND OBLIGATIONS OF AN ASSOCIATED ORGANIZATION AND THE COUNCIL**

### **§ 6.**

1. Associated Organizations shall participate in the works of the Council free of charge.
2. In the case of a conflict of interests of the Foundation with the interests of a member of the Associated Organization's authorities, his or her spouse, family and relatives up to the second degree, and persons who remain in such a relationship with him or her that there may be doubts about his or her impartiality, the Associated Organization shall refrain from issuing an opinion on such matters, and this fact shall be reported to the President of the Council of the Foundation.

### **§ 7.**

1. Associated Organizations participating in the works of the Council shall have the following rights:
  - 1) the right to present their opinion on matters being the object of the works of the Council;
  - 2) the right to participate in the works of advisory teams and working groups appointed by the Council, in accordance with the Regulations.
2. The Associated Organization shall authorize one person to participate in the works of an advisory team or working group appointed by the Council of the Foundation. The authorization to participate in the works of the advisory team or working group should be submitted in writing.
3. Instead of inviting the Associated Organization to participate in the works of the advisory team or working group, the Council may appoint a person designated by the Associated Organization to the advisory team or working group.

### **§ 8.**

The Associated Organization shall be obligated to:

- 1) observe the basic principles, as referred to in § 4 of the Regulations;
- 2) observe the principles of confidentiality, as defined in Appendix No 1 to these Regulations.

### **§ 9.**

1. The Council shall be entitled to request the Associated Organization for its opinion on any matter being the subject of the Council's works.
2. In the following matters:
  - 1) approval for arranging calculation and fee amounts for System usage (including changing the method of calculation and fee amounts);
  - 2) approval for arrangement and modification of the rules on prohibition of disclosure of data processed in the System;

- 3) approval to deviate from the principles set out in the Blueprint;
- the Council shall be entitled to request the Associated Organization's opinion.
3. The Council shall be entitled to set a deadline for the Associated Organization to present its opinion. The deadline shall, if possible (depending on the urgency of the matter), enable the Associated Organizations to analyse the issue.
  4. The Council, when requesting the opinion, shall, if possible, provide the Associated Organizations with materials on the issue in question.
  5. The Council, when deciding on matters on which it requested the Associated Organizations' opinion, shall be obligated to consider the opinions presented.
  6. In justified cases, the Council may request the Associated Organization to elaborate on the opinion presented or to provide further explanation.

### **§ 10**

The Council may invite (and in the cases regulates by law shall actually invite) the Associated Organizations to participate in the works of advisory teams and working groups appointed by the Council, or it may appoint a person designated by the Associated Organization as a member of the advisory team or the working group.

## **CHAPTER 5. RULES FOR COMMUNICATION WITH ASSOCIATED ORGANIZATIONS**

### **§ 11**

1. The Management Board shall share with any interested organizations the materials necessary to apply for the status of an Associated Organization. In particular, the Management Board shall share the Statute and these Regulations. The materials, as referred to above, may be shared in electronic form.
2. The Management Board shall be responsible for maintaining communication between the Council and the Associated Organizations. The Management Board in particular:
  - 1) submits to the Council the interested organizations' applications for the status of an Associated Organization;
  - 2) informs the interested organization of the decision of the Council as regards the application for the status of an Associated Organization, and notifies the organization if any required information is missing;
  - 3) forwards to the Associated Organization the Council's invitation to participate in the works of advisory teams and working groups;
  - 4) forwards to the Associated Organizations the Council's requests for an opinion and then forwards the opinions received to the Council;
  - 5) informs the Associated Organizations of changes in the Regulations, including changes in the

principles of confidentiality, as defined in Appendix No 1.

3. The Management Board may communicate with the Associated Organizations in writing or in electronic form.
4. An Organization that consents to receiving electronic communications shall inform the Management Board of its current e-mail address in writing.

## **CHAPTER 6. LOSS OF THE ASSOCIATED ORGANIZATION STATUS**

### **§ 12**

1. The status of an Associated Organization shall expire if:
  - 1) the Associated Organization submits an application for ending its participation in the works of the Council;
  - 2) the Associated Organization ceases to exist or is removed from a relevant register.
2. In the situations indicated in § 12 section 1 of the Regulations, the Council shall deem that the status of an Associated Organization has been lost.
3. If an Associated Organization loses its status of an Associated Organization, it shall be obligated to return all materials or declare in writing that the materials have been destroyed.

### **§ 13**

1. The Council may decide to exclude an Associated Organization from participation in the works of the Council if the Associated Organization is in breach of:
  - 1) the basic principles, as referred to in § 4 of the Regulations;
  - 2) the principles of confidentiality, as defined in Appendix No 1 to these Regulations.
2. The Associated Organization shall be informed if the Council's meeting agenda includes an item related to the decision to exclude the Associated Organization from participation in the works of the Council. The Associated Organization shall be entitled to present its opinion in the above scope.
3. The Council's decision to exclude an Associated Organization from participation in the works of the Council requires justification.
4. The Council's decision to exclude an Associated Organization from participation in the works of the Council shall not prevent the organization from re-applying for the status of an Associated Organization.
5. In less important matters, the Council may issue a warning or suspend the Associated Organization's right to participate in the works of the Foundation.
6. In the case of suspension of the Associated Organization's right to participate in the works of the Foundation, the Council shall also define the period of suspension.

### **§ 14**

1. In the case of excluding the Associated Organization from participation in the works of the Council or expiration of the Associated Organization status, the organization may apply for the re-examination of its case.
2. The application, as referred to in section 1, shall be processed by the Council within 30 days.

## **CHAPTER 7. FINAL PROVISIONS**

### **§ 15**

1. These Regulations shall come into force on the day of their adoption by the Council.
2. The Regulations may be amended by a resolution of the Council. The amendment of the Regulation shall come into force on the date indicated by the Council, not earlier however than after two weeks of informing the Associated Organizations.

to the Regulations defining the principles of relations and cooperation with Associated Organizations of the National Medicines Verification System Foundation.

### **PRINCIPLES OF CONFIDENTIALITY**

1. This Appendix No 1 to the Regulations defining the principles of relations and cooperation with Associated Organizations (“**Regulations**”) of the National Medicines Verification System Foundation with its seat in Warsaw (“**Foundation**”), entitled Principles of Confidentiality (“**Principles**”), constitutes an integral part of the Regulations.
2. The Associated Organization shall be obligated to treat as “**Confidential Information**” all information obtained during and in relation to participation in the works of the Council of the Foundation, in particular any financial, trade, organizational, legal, IT and technical information, whereas information shall mean any communication, expressed orally, in writing, by an image, drawing, sign, sound or stored in a device, instrument or other object, and expressed in any other way.
3. Confidential Information shall not include information that:
  - 1) had been known to the Associated Organization prior to the date on which the Council of the Foundation passed its resolution to allow the Associated Organization to participate in the works of the Council of the Foundation;
  - 2) is publicly available for reasons other than due to disclosure in breach of these Principles or the law;
  - 3) has been obtained by the Associated Organization from third parties, unless the Associated Organization was aware that these third parties received that information in violation of the law, these Principles or obligations related to such information;
  - 4) was disclosed with the consent of the Council of the Foundation expressed by way of resolution.
4. Any obligations resulting from these Principles shall be applicable to the given Associated Organization from the date on which the Council of the Foundation passed the resolution to allow the Associated Organization to participate in the works of the Council of the Foundation for 5 years from the date of the expiry of the status of a given Associated Organization or exclusion of the Associated Organization from participation in the works of the Council.
5. An Associated Organization whose status has expired or which has been excluded from the works of the Council shall be obligated to return to the Foundation within 30 days any Confidential Information along with the media on which such Information is stored.
6. The Associated Organization shall be obligated to:
  - 1) keep in strict confidentiality any Confidential Information and refrain, subject to item 5)

- below, from disclosing the Confidential Information to any other person;
- 2) protect Confidential Information, in particular to take every effort to protect it against any form of unauthorized access or against loss;
  - 3) use the Confidential Information strictly for purposes related to participation in the works of the Council of the Foundation and to refrain from using the Confidential Information for any other purpose;
  - 4) refrain from using the Confidential Information in a way that may threaten or harm the interests of the Foundation, bring any losses for the Foundation or the reputation of the Foundation, or for any personal purposes not related to participation in the works of the Council of the Foundation;
  - 5) refrain from disclosing, without prior written consent of the Foundation, any Confidential Information to any persons other than key personnel, advisors or associates of the Associated Organization, involved in participation in the works of the Council of the Foundation that shall be authorized to use the Confidential Information solely for the purposes related to participation in the works of the Council of the Foundation; The Associated Organization shall be responsible for the actions and omissions of its key personnel, advisors and associates as for its own actions or omissions;
  - 6) ensure that any persons authorized on the part of the Associated Organization to receive Confidential Information, in accordance with item 5) above, have been duly informed and notified of the confidential character of any Confidential Information disclosed to them and have been obligated to observe its confidential character in accordance with the provisions of these Regulations.
7. If the Associated Organization is required to disclose the Confidential Information in whole or in part based on a judgement or decision of a competent court or another public administration body or yet another authorized body, to whose authority it is subject, the Associated Organization shall be obligated to, provided that it is legally permissible:
- 1) immediately inform the Foundation of such request and its circumstances;
  - 2) consult the Foundation as regards taking available legal steps to reject or limit the scope of such request;
  - 3) if the disclosure of Confidential Information is necessary or is deemed intentional — take every effort to obtain reliable assurance that the Confidential Information will not be further disclosed.

to the Regulations defining the principles of relations and cooperation with Associated Organizations  
of the National Medicines Verification System Foundation.

**TEMPLATE OF THE FORM FOR REQUESTING THE STATUS OF AN ASSOCIATED  
 ORGANIZATION**



**AN APPLICATION FOR GRANTING THE STATUS OF AN ASSOCIATED  
 ORGANIZATION**

<b>APPLICANT</b>			
Name			
Legal form (e.g. limited liability company, association, foundation)			
Registered office address (street, building No, premises No, postal code, city, country)			
Correspondence address (street, building No, premises No, postal code, city, country)			
National Court Register number and designation of the register court or number of the relevant register and register designation			
TAX ID No (NIP)		STATISTICAL ID No (REGON)	
e-mail: (optional)		Telephone (optional)	

fax: (optional)		website (optional)	
Dedicated contact person			
Contact person's e-mail address  (optional)		Contact person's telephone No  (optional)	

Acting on behalf of the Applicant:

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(Name)

I (we) request that the Applicant be granted the status of an Associated Organization and, at the same time, be allowed to participate in the works of the Council of the National Medicines Verification System Foundation with its registered office in Warsaw ("Foundation").

At the same time, I (we) declare that:

1. The Applicant meets all the requirements to be granted the status of an Associated Organization and, at the same time, to participate in the works of the Council of the Foundation;
2. The Applicant is familiar with and agrees to be bound by the Statute of the Foundation;
3. The person (persons) signing this application has (have) been duly authorized.

<b>APPENDICES</b>	
1) A statement of will of the statute bodies of the Applicant regarding participation in the works of the Council of the Foundation, in writing and with a certified date	<input type="checkbox"/>
2) The Statute or other appropriate document indicating the object of the Applicant's activities	<input type="checkbox"/>
3) The current (i.e. issued within the last three months) excerpt from a relevant register to which the Applicant has been entered (e.g. National Court Register)	<input type="checkbox"/>
4) Justification of the Application	<input type="checkbox"/>

<p>5) Declaration of familiarity with these Regulations defining the principles of relations and cooperation with Associated Organizations of the Foundation, along with an official declaration to:</p> <p style="padding-left: 40px;">a. observe the basic principles, as referred to in § 4 of the Regulations;</p> <p style="padding-left: 40px;">b. observe the principles of confidentiality, as defined in Appendix No 1 to these Regulations.</p>	<input type="checkbox"/>
<p>6) Power of attorney to submit the application (if applicable)</p>	<input type="checkbox"/>

<b>SIGNATURE</b>	
city, date	name, surname and signature of the person (persons) authorized to represent the Applicant

The application, along with the appendices, must be submitted in writing to the address of the registered office of the Foundation (ul. Sienna 39, 00-121 Warszawa)