Regulations of the Medical Research Agency Council

Clause 1

General Provisions

1. These Regulations specify the organization and manner of implementation of tasks by the Medical Research Agency's Council, hereinafter referred to as "the Council".

2. The Council shall serve as a consultative body.

3. The Council shall be responsible for issuing opinions on:

1) prospective directions of activity of the Medical Research Agency, hereinafter referred to as "the Agency";

2) the rules for the distribution of funds included in the Agency's annual financial plan;

3) the Agency's annual financial plan and changes thereof;

4) the Agency's annual operating plan and changes thereof;

5) the Agency's annual financial statements;

6) the annual report on the Agency's activities, together with information on the results of the evaluation referred to in Article 23 of the Medical Research Agency Act of 21 February 2019 (Journal of Laws, item 447);

7) draft Charter of the Agency and draft amendments thereto;

4. Opinions on the matters referred to in subclause 3(1) to (7) shall be issued within 30 days after receipt of the relevant application.

5. In order to perform its tasks, the Council shall be entitled to inspect the financial records kept by the Agency and to request from the President of the Agency to provide any necessary information regarding these records.

6. Council Members shall be elected in accordance with the Medical Research Agency Act of 21 February 2019, hereinafter referred to as "the Act".

7. The Council shall be composed of 15 to 20 members appointed and dismissed by the minister competent for health matters.

8. If invited by the Chairperson, non-members may participate in the work of the Council without the right to vote and to be present during voting. The provisions of Clause 4(4) and (5) shall apply accordingly.

9. The Council shall make decisions by a simple majority of votes, in an open vote, in the presence of at least 8 members of the Council.

10. The Council may adopt resolutions by circulation.

11. If justified by the need to ensure that the tasks referred to in subclause 3 are performed in an efficient manner, the Chairperson may, upon consultation with the Council members, appoint standing or working committees, their members and specify the scope of tasks delegated to them.

12. The first meeting of the newly appointed committee shall be convened by the Chairperson of the Council.

13. A chairman and a vice-chairman of each standing or working committee should be elected from among committee members.

14. In the event of any such change in the composition of the Council which affects the composition of a standing or working committee, or at the request of any Council member, the Chairperson shall change the composition of such standing or working committee within 14 days.

Clause 2

Chairperson of the Council and his Deputy

1. The work of the Council shall be directed by the Chairperson elected by the Council from among its Members by an absolute majority of votes, in a secret vote, in the presence of at least half of the Council Members.

2. The newly appointed Council shall elect the Chairperson at the first meeting.

3. Persons standing as candidates for a chairperson shall be proposed by the Council Members at the meeting.

4. If the Council does not elect a Chairperson in two subsequent voting rounds, the Chairperson shall be nominated by the minister competent for health matters from among its members.

5. Following the election of the Chairperson of the Council, his Deputy shall be elected. At the meeting, the Council Members shall propose candidates as the Deputy to be elected by an absolute majority of votes in the presence of at least half of the Council Members.

6. If the minister competent for health matters appoints the Council for a new term of office or the former Chairperson of the Council has been dismissed or resigned from his office, the Council shall elect a new Chairperson. The provisions of subclauses 1 and 2 shall apply accordingly.

7. In the case referred to in subclause 4, until such time as the Chairperson of the Council is elected, the Council's sessions shall be presided over by the Chairperson of the last Council and, in his absence, by his Deputy, and, in the latter's absence, by the most senior Council Member.

8. While performing his duties, the Chairperson of the Council may not proceed against resolutions which have been adopted by a majority of votes of the Council members as relevant for a given matter.

9. The Council may dismiss the Chairperson and his Deputy from their office before the end of the term of office.

10. A motion for dismissal of the Chairperson or his Deputy shall be submitted in writing and should set out detailed reasons and identify a candidate for a new Chairperson or his Deputy.

11. A motion for dismissal of the Chairperson or his Deputy may be submitted by any Council Member to the MRA President no later than 3 days in advance of the Council meeting.

12. Dismissal of the Chairperson or his Deputy shall take effect at the Council meeting, in a secret vote, by an absolute majority of votes. With an equal number of votes "for" and "against", a resolution on dismissal shall be rejected.

Clause 3

Term of Office of the Council

1. Council Members shall be appointed for the term of office of the Council, which lasts 6 years.

2. The term of office of a Council Member shall commence on the date of his appointment and shall end upon expiry of the term of office of the Council.

3. A Council Member who has replaced the Council Member whose mandate has expired shall remain in office until the end of the term of office of the Council.

4. Each Council Member may resign from office without giving a reason. A letter of resignation should be submitted to the minister competent for health matters through the President of the Agency.

5. The same person may serve as a Council Member for no longer than two consecutive terms of office. The office of a Council Member cannot be combined with the office of an expert appointed by the President of the Agency to the application evaluation team which is appointed in the course of the competition referred to in Article 16 of the Act.

Clause 4

Obligations of Council Members

1. Attendance at Council meetings shall be the obligation of any Council Member.

2. A Council Member is obliged to attend Council meetings and inform the Chairperson and the Agency's Office of any planned absence in writing or via email.

3. Council Members shall exercise their rights and perform their obligations in person.

4. Council Members are obliged to disclose any factual or legal circumstance that prevents them from fulfilling their tasks in an impartial manner. Council Members are in particular obliged to disclose a conflict of personal interest with the public interest or the interest of the Agency.

5. A Council Member is obliged to maintain confidentiality with respect to any information and documents which he may have obtained as a Council Member, designated as "for internal use".

- 6. A decision whether to classify individual information and documents as information and documents intended for internal use only shall be made by:
- 1) the Chairperson of the Council with regard to information and documents developed in the course of the Council's work;
- 2) the President of the Agency or a person authorized by him with regard to other information and documents that are submitted to the Council.
- 7. Individual information and documents shall be assigned the status of documents intended for internal use only through one of the following methods:
- 1) affixing a notice reading "for internal use" to the document;
- 2) making an appropriate reservation in the content of the email providing specific information and documents to the Council members;
- 3) providing information at a meeting of the Council or its Committee.

8. The confidentiality obligation shall not apply to information that is required to be provided under the generally applicable Polish law, that is generally known to the public or whose disclosure by the Council Member has been authorized by the President of the Agency.

9. The Chairperson of the Council shall be responsible for directing the work of the Council in accordance with its scope of operation and the Regulations.

10. The Chairperson of the Council shall in particular:

- a) organize the work of the Council,
- b) represent the Council vis-à-vis third parties,
- c) convene Council meetings,
- d) preside over Council meetings,
- e) draft and present the agenda for approval,
- f) appoint standing or working committees,
- g) sign minutes of Council meetings.

11. The Deputy shall be responsible for replacing and assisting the Chairperson of the Council in performing the tasks referred to in subclause 8.

Clause 5

Council Meetings

1. The Council shall meet at least at quarterly intervals.

2. Council meetings shall be convened by the Chairperson of the Council. This shall not restrict the right of the President of the Agency to convene a Council meeting.

3. The first meeting of the Council of the new term of office shall be convened by the President of the Agency.

4. The Chairperson of the Council shall promptly inform the President of the Agency of a Council meeting being convened.

5. Any correspondence sent to the Council Members, including notices of a Council meeting, shall be sent by registered mail or, with the consent of the Council Member, to the email address provided to the Agency's Office. In such case, correspondence shall be deemed delivered if the sender has received an electronic confirmation that the sent information had been displayed on the recipient's screen or if the recipient has confirmed via email that they had received the correspondence.

6. The President of the Agency or the minister competent for health matters may participate in Council meetings without voting rights.

Clause 6

Council Meetings and Minutes

1. The Chairperson of the Council shall direct the course of the Council meeting. In his absence, the course of the meeting shall be directed by the Deputy Chairperson, and, in his absence, the most senior Council Member.

2. Proposals for the agenda of the meeting may be submitted to the Chairperson of the Council by all Council Members and the President of the Agency via email to the address of the Chairperson of the Council no later than 7 days in advance of the date of the Council meeting, unless the Chairperson consents to these proposals being submitted at a later date.

3. The Council shall make decisions by a simple majority of votes, in an open vote, in the presence of at least 8 members of the Council. This shall not preclude the Council from adopting resolutions by circulation or means of direct communication at a distance.

4. At Council meetings, voting shall be open, by a show of hands, subject to the voting referred to in Clause 2(2) and (12).

5. The Council may invite other persons to attend its meetings in order to provide expert assistance in matters covered by the agenda of the meeting, without the right to vote and to be present during voting. The provisions of Clause 4(4) shall apply accordingly.

6. Minutes shall be kept of all Council meetings. The secretary of the meeting appointed by the Chairperson or his Deputy shall draw up minutes based on the course of the meeting recorded by means of voice and/or image recording equipment. The record referred to in the preceding sentence is solely and exclusively intended to reconstruct the course of the meeting and the arrangements made during the meeting. It may neither be published nor shared with third parties.

7. Minutes of a Council meeting should include:

a) the date and place of the meeting;

b) the list containing the participants' names;

c) the agenda of the meeting;

d) the text of resolutions adopted by the Council;

e) such other arrangements as may be made by the Council.

8. Draft minutes, approved by the Chairperson, shall be circulated electronically amongst all Council Members for approval in advance of the next Council meeting.

9. Each Council Member may request that his motions and statements be recorded in, and also enclosed with, the minutes if they were made in writing during the meeting.

10. A Council Member who has attended the meeting may electronically submit comments to the minutes within 7 calendar days following their circulation date.

11. The absence of comments shall be taken as consent to the minutes being approved and signed by the Chairperson at the next Council meeting.

12. If the comments referred to in subclause 10 are made, the Chairperson shall direct to have revisions incorporated, if any.

13. In the case referred to in subclause 12, a revised version of the minutes shall be circulated electronically amongst Council Members.

14. If the Chairperson does not accept the comments referred to in subclause 10 or if at least 3 (three) Council Members make reservations to the same item of the revised version of the minutes, the issue shall become the subject of discussion at the next Council meeting and should be resolved by the Council in the form of a position.

15. With regard to the committees referred to in Clause 1(10), the provisions of subclauses 7 to 14 shall apply accordingly.

16. The Chairperson shall promptly forward minutes of the Council and committee meetings to the Agency's Office within 7 days following the date of adoption, where they are to be stored.

Clause 7

Procedure for Adopting Resolutions

1. The Council may adopt resolutions in writing, by circulation or by means of direct communication at a distance.

2. The Council's opinions and positions shall be issued by means of a resolution to be adopted by a simple majority of votes, in an open vote, in the presence of at least 8 members of the Council.

3. In the case of adopting resolutions by circulation, the text of the resolutions should be forwarded to the Council Members via email in the manner specified in Clause 5(5). Once the text of the resolution has been forwarded and provided that no objection has been raised thereto, the resolution shall be sent for signature by all Council Members. By affixing their signature under the text of the resolution, the Council Members vote for or against the resolution. It shall also be allowed to vote on a resolution by electronic means.

4. In the event of resolutions being adopted by means of direct communication at a distance, one or more Council Members shall connect with the Chairperson via telephone, Internet or other links enabling the persons attending the Council meeting by means of remote communication to be identified. The Chairperson shall read out or electronically deliver to the Council Members attending the meeting the text of the resolutions, whereupon votes for or against the resolution shall be cast.

5. A resolution shall be considered to have been adopted by circulation if an opinion on the text of the resolution is given in writing or electronically by at least half of the Council members and the text of the resolution is taken by the absolute majority of them without reservations.

6. At the next Council meeting, the Chairperson shall inform the Council members of the resolution being adopted by circulation.

Clause 8

Miscellaneous

1. The Agency's Office shall provide the Council with technical and organizational support.

2. In order to ensure the expedient and effective course of the Council meeting, the Agency's Office is required to send to the Council Members, in advance of each Council meeting, a set of materials necessary to give effect to the scheduled agenda of the Council meeting.

3. Promptly upon receipt of a notice of appointment, individuals standing as candidates for Council Members are required to communicate to the Agency's Office their mailing addresses, telephone numbers or email addresses to which information about the Council meetings and any other correspondence sent by the Agency's Office will be delivered or forwarded.

4. Council Members shall promptly inform the Chairperson of the Council and the Agency's Office of any change of their respective telephone numbers or mailing or electronic addresses.

5. If a Council Member fails to comply with the obligation referred to in subclause 4, any correspondence shall be deemed duly delivered if it has been sent to the mailing or email address provided to the Agency's Office in accordance with subclause 3.

Clause 9

Final Provisions

1. These Regulations shall take effect on the date a resolution is adopted by the Council.

2. These Regulations shall be published in the Agency's Public Information Bulletin.