

RULES OF PROCEDURE OF THE NATIONAL COUNCIL FOR PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS AND ITS ADMINISTRATION

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Chapter one. GENERAL PROVISIONS

Art. 1. (1) The Rules shall regulate the structure and the organization of the work of the National Council for the Pricing and Reimbursement of Medicinal Products, hereinafter referred to as "the National Council", and of its administration.

(2) The National Council shall have the status of a State Commission.

Art. 2. (1) (Amend. – SG, 26/19, in force from 01.04.2019) The National Council shall be a state body under the Minister of Health, which shall:

1. approve and register the prices of medicinal products;
2. include, modify or exclude medicinal products from the Positive Medicinal List (PML);
3. update the PML as well as the register of the limited and maximum sales prices of medicinal products;
4. carry out health technology assessments of medicinal products;
5. maintain the reimbursement status of medicinal products;
6. determine the medicinal products, for which the effect of therapy is monitored;
- 6a. (new – SG, 28/21) carry out an analysis of the information, collected from the medical institutions on the medicinal products, for which the effect of therapy is monitored;
7. approve, revoke or amend pharmacotherapeutic guidelines under Art. 259, Para. 1, item 4 of the Act on Medicinal Products in Human Medicine (AMPHM);
8. carry out information, publishing and research-scientific activities, related to pricing, reimbursement and medicines policy;
9. control the prices of medicinal products in accordance with the AMPHM;
10. assist in negotiating concessions under Art. 45, Para. 10, 13 and 21 of the Health Security Act for medicinal products, for which applications for inclusion in the PML have been submitted;
11. (New – SG, 28/21) generate a unique national identification number for each medicinal product and enter it in the register, referred to in Art. 259, Para. 2, item 4 of the AMPHM.

(2) (Amend. – SG, 24/14) The National Council shall be a legal entity on budgetary spending with its seat in Sofia - a secondary budget spending administrator under the Minister of Health.

Art. 3. (1) The National Council shall be a collegial body, consisting of a Chairperson and six members.

(2) The Chairperson and members of the National Council shall be elected and dismissed by the Council of Ministers upon the proposal of the Minister of Health.

Art. 4. (1) The activities of the National Council shall be serviced by its administration.

(2) The administration of the National Council shall be headed by a Chief Secretary.

Art. 5. (1) Permanent and temporary advisory units may be established within the National Council.

(2) The National Council may involve external experts for the implementation of its activities.

Art. 6. In carrying out its functions, the National Council shall interact with state authorities and institutions, as well as with local self-government bodies and non-governmental organizations.

Chapter two.

POWERS OF THE CHAIRPERSON

Art. 7. (1) The Chairperson shall direct, coordinate and control the activities of the National Council and represent it.

(2) The Chairperson of the National Council shall:

1. convene and preside the meetings of the National Council;
2. issue penal decrees in the cases, provided for in the AMPHM;
3. conclude, amend and terminate employment and service relationships with persons in the administration;
4. be responsible for the management of financial resources and for their lawful and appropriate expenditure;
5. conclude contracts, necessary for the operation of the National Council and its administration;
6. conclude civil contracts with the external experts referred to in Art. 5, Para. 2;
7. send staff to mission trips;
8. (new – SG, 23/15, in force from 27.03.2015) approve the job descriptions, internal rules, as well as standard operating procedures and instructions for the work of the administration of the National Council;
9. (new – SG, 26/19, in force from 01.04.2019) establish by order permanent and temporary advisory units, related to the activities of the National Council;
10. (former item 8 – SG, 23/15, in force from 27.03.2015, former item 9 – SG, 26/19, in force from 01.04.2019) also perform other functions, provided for by an Act or by a legislative instrument.

(3) The Chairperson of the National Council shall submit an annual report on the activities of the National Council to the Council of Ministers.

(4) In the absence of the Chairperson, he shall be replaced by a member of the Council, appointed by him by an order in each case.

(5) (New – SG, 26/19, in force from 01.04.2019) The Chairperson of the National Council may - by an order - entrust the Chief Secretary with the execution of the powers under Para. 2, items 5 - 7.

Chapter three.

ORGANISATION OF THE OPERATION OF THE NATIONAL COUNCIL

Art. 8. (1) The National Council shall consider and decide on matters within its competence at meetings.

(2) The Chairperson of the National Council shall designate a member(s) of the Council, who shall prepare and submit to the Council an expert report on each requested procedure in accordance with the Ordinance under Art. 261a, Para. 5 of the AMPHM.

Art. 9. (1) The meetings of the National Council shall be open and closed.

(2) The National Council shall designate the officials of the administration, a representative of the National Health Insurance Fund or the Ministry of Health, who must attend the open meetings.

(3) The open meetings may be attended by representatives of professional organizations, applicants pursuant to the Ordinance under Art. 261a, Para. 5 of the AMPHM, manufacturers of medicinal products, representative patient organizations and other persons, who shall be notified of the date and time of the meeting under the conditions and procedure, determined by the Council.

(4) Only the members of the National Council and the recording secretary shall participate in a closed meeting. Other persons may also be present at a closed meeting by decision of the Council.

Art. 10. (1) The meetings of the National Council shall be regular and extraordinary.

(2) The National Council shall meet regularly once a week on a previously published agenda. The agenda materials shall be made available to the members at least two days before the meeting.

(3) The National Council shall be convened in an extraordinary meeting by the Chairperson on his own initiative or on the proposal of any of its members.

(4) Matters of an urgent nature, not included in the agenda may be discussed at meetings, provided that no member of the National Council objects to the additional matters being discussed at the meeting.

(5) (New – SG, 28/21) Exceptionally and upon the proposal of the Chairperson, the National Council may hold its meetings on-line.

Art. 11. (1) The meetings of the National Council shall be opened and held in the presence of more than half of the total number of its members.

(2) Meetings of the National Council shall be presided by the Chairperson and in his absence by an authorized member of the National Council, referred to in Art. 7, Para. 4.

(2) The meetings of the National Council shall be chaired by the Chairperson and in his absence by an authorized member of the National Council, as referred to in Art. 7, Para. 4.

(3) (New – SG, 28/21) Where the meeting is held on-line, pursuant to Art. 10, Para. 5, it shall be provided virtually with the possibility of attendance of the members of the National Council, subject to the quorum requirements.

Art. 12. (1) The National Council shall adopt its decisions by an open vote and by a majority of more, than half of its total members.

(2) The decisions of the National Council shall be communicated in writing to the persons concerned within the time limits laid down in the Code of Administrative Procedure.

(2) The decisions of the National Council shall be communicated in writing to the persons concerned within the time limits, laid down in the Administrative Procedure Code.

Art. 13. (1) (Former text of Art. 13 – SG, 28/21) Minutes shall be kept for each meeting of the National Council and shall be signed by the Chairperson, or the person, referred to in Art. 7, Para. 4 and by all members present

(2) (New – SG, 28/21) Minutes shall also be prepared in the cases of a meeting, held on-line, pursuant to Art. 10, Para. 5, and the minutes shall be signed with qualified electronic signatures.

Art. 14. (1) Employees and other persons, participating in the activities of the National Council shall be obliged to protect the professional and commercial secrets, which come to their knowledge in connection with their work.

(2) Employees shall sign a declaration, that they will keep official and commercial secrets. The content of the declaration shall be determined by the National Council.

Art. 15. In exercising their supervisory functions, the members of the National Council and its designated officials shall have the right to:

1. free access to the office premises of the persons under its control;
2. collect documents and written explanations from the inspected persons.

Chapter four.

ORGANISATIONAL STRUCTURE OF THE ADMINISTRATION

Art. 16. (1) (Amend. – SG, 23/15, in force from 27.03.2015, amend. – SG, 26/19, in force from 01.04.2019) The structure of the administration shall comprise: Chief Secretary, Directorate for Administrative and Legal Services and Financial Activities, Directorate for Regime Management and Health Technology Assessment and Directorate for Analytical Activities and Control.

(2) (Amend. – SG, 24/14, amend. - SG 84/14, in force from 10.10.2014, amend. – SG, 26/19, in force from 01.04.2019) The total number of staff of the National Council and its administration shall be 44 persons.

(3) The number of the individual organizational structures and administrative units is set out in the Annex.

Art. 17. (Amend. – SG, 26/19, in force from 01.04.2019) The general administration of the National Council shall be organized in the Directorate of Administrative-Legal Services and Financial Activities.

Art. 18. (Amend. – SG, 26/19, in force from 01.04.2019) The specialized administration shall be organized in the Directorate for Analytical Activities and Control and the Directorate for Regime Management and Health Technology Assessment.

Chapter five.

FUNCTIONS OF THE ADMINISTRATION

Section I.

Functions of the Chief Secretary

Art. 19. (1) (Former text of Art. 19 – SG, 26/19, in force from 01.04.2019) The Chief Secretary shall:

1. direct, coordinate and supervise the functioning of the general and specialized administration in order to ensure, that legislative acts are complied with;
2. draw up proposals for the job descriptions;
3. approve the job descriptions of staff;
4. propose the structuring and restructuring of administrative units;
5. be responsible for the working conditions of the National Council and its administration and for the organizational and technical equipment of the units;
6. convene at its discretion meetings of the senior civil servants of the units concerned to discuss various matters and be responsible for their implementation;
7. draw up the draft budget account of the National Council as regards the funds, required for the administrative support of the National Council's activities;
8. ensure, that the financial and material resources, made available to the National Council are spent lawfully and appropriately;
9. (amend. – SG, 28/21) be responsible for the organization of the activities, related to the complaints and signals of citizens and organizations, received by the National Council;
10. control the document flow in the National Council, as well as the functional implementation of the individual units, respectively the compliance with the duties of the employees in the administration, in accordance with the provisions in force;
11. (suppl. – SG, 28/21) organize the preparation of an annual report on the state of the administration, planning and accountability in the implementation of the annual objectives of the administration;
12. organize, coordinate and supervise the handling and preservation of the documents and archives of the National Council;
13. (new – SG, 26/19, in force from 01.04.2019) direct the process of automation and computerization of the National Council management.

(2) (New – SG, 26/19, in force from 01.04.2019) In the absence of the Chief Secretary, his/her functions may be performed on a case-by-case basis by a Director of a Directorate, designated by the Chairperson of the National Council.

Section II.

General administration

Art. 20. (Amend. – SG, 26/19, in force from 01.04.2019) Directorate for Administrative and Legal Services and Financial Activities shall:

1. prepare the budget forecast and the draft budget of the National Council for the respective year;

2. organize, implement and control the financial and accounting activities, monitor the implementation of the budget, the lawful expenditure of funds and the use of the assets of the National Council and ensure the organization of the implementation of the legal acts in the field of public procurement;

2a. (new – SG, 28/21) assist the Chairperson in the organization and establishment of the financial management and control system;

2b. (new – SG, 28/21) ensure the timely collection of contributions;

3. be responsible for the legality of draft orders, documentation for procedures under the Public Procurement Act and contracts, to which the National Council is a party;

4. organize and implement the management of assets, material and technical supplies, the implementation of defense-mobilization training and crisis management activities, ensure healthy and safe working conditions, as well as the security and access regime in the administrative premises of the National Council;

5. draw up acts and documents, relating to the establishment, amendment and termination of service and employment relationships with employees;

6. draw up the job and name schedules of the National Council administration;

7. organize and implement human resources management activities in accordance with the normative and internal acts, plan and organize activities to build and develop the administrative capacity of the National Council;

7a. (new – SG, 28/21) organize the overall activities of the administrative services through the Administrative Service Centre, including electronically;

8. examine signals and complaints, relating to administrative services;

9. organize and carry out the clerical and archival work in the National Council;

10. maintain and update the National Council's website;

11. prepare, coordinate and protocol public appearances of the Chairperson and/or officials, authorized by the Chairperson at press conferences, official and working meetings and maintain protocol correspondence;

12. organize, coordinate and maintain relations with similar bodies in other countries and with international organizations, related to the regulation of prices of medicinal products;

13. (amend. – SG, 23/15, in force from 27.03.2015) organize and maintain the local networks, communication equipment, computer and peripheral equipment, etc.;

14. (new – SG, 23/15, in force from 27.03.2015, suppl. - SG 28/21) organize the design, construction, implementation, maintenance and use of automated information systems, information and communication technologies and information databases, including responsibility for the introduction and implementation of systems, related to e-government and the introduction of rules for information security and interoperability of data, exchanged between administrations;

15. (new – SG, 23/15, in force from 27.03.2015) ensure automated exchange of data with information systems of the state administration and other departments;

16. (new – SG, 23/15, in force from 27.03.2015) develop and implement rules for information management, information security, information access system, etc.;

17. (new – SG, 26/19, in force from 01.04.2019, amend. – SG, 28/21) organize and coordinate the process of access to public information and prepare legal opinions and draft decisions under the Access to Public Information Act;

18. (new – SG, 26/19, in force from 01.04.2019) provide legal and normative services to the National Council, as well as perform legal representation before the courts and other jurisdictions upon written authorization by the Chairperson of the National Council;

19. (new – SG, 26/19, in force from 01.04.2019) summarize and analyze the results of the cases, draw conclusions and propose measures to eliminate violations of law and to hold the guilty persons accountable;

20. (new – SG, 26/19, in force from 01.04.2019) draw up opinions or develop proposals for solutions to legal problems, related to the activities of the National Council;

21. (new – SG, 26/19, in force from 01.04.2019) give opinions on draft legal acts, related to the activities of the National Council;

22. (new – SG, 26/19, in force from 01.04.2019) organize the study of the results of the implementation of the normative acts, related to the activities of the National Council and, if necessary, make proposals for their improvement or for taking measures for their proper implementation;

23. (new – SG, 26/19, in force from 01.04.2019) prepare or give opinions on the legality of draft contracts, orders and other acts and documents, related to the activities of the National Council;

24. (new – SG, 26/19, in force from 01.04.2019) ensure the proper functioning and maintain the Administrative Information System (AIS) and electronic public registers;

25. (new – SG, 23/15, in force from 27.03.2015, former item 17 – SG, 26/19, in force from 01.04.2019) carry out other activities, arising from the decisions of the National Council and from the orders of the Chairperson and the Chief Secretary.

Section III. Specialized Administration

Art. 21. (Amend. – SG, 26/19, in force from 01.04.2019) Directorate of Regime Management and Health Technology Assessment shall:

1. prepare the agenda for the meetings of the National Council in consultation with the Chairperson

2. organize the preparation of the meetings of the National Council;

3. prepare the minutes of the meetings and the decisions of the National Council;

4. carry out a legal assessment of the applications, submitted to the National Council for the procedures, referred to in Art. 261a, Para. 5 of the AMPHM;

5. (amend. – SG, 26/19, in force from 01.04.2019) organize the activities of the Council, related to the evaluation of applications for maintaining the reimbursement status of medicinal products;

6. (amend. – SG, 26/19, in force from 01.04.2019) organize and support the activity, related to the monitoring of the effect of therapy with medicinal products;

7. draft criminal rulings;

8. (amend. – SG, 26/19, in force from 01.04.2019) organize/participate in the activity on preparation of medical and pharmaco-economic evaluation of medicinal products;

9. (amend. – SG, 26/19, in force from 01.04.2019) organize/participate in the activities, related to the health technology assessment of medicinal products;

10. (amend. – SG, 26/19, in force from 01.04.2019, amend. – SG, 28/21) organize activities, related to the adoption, revocation or amendment of pharmacotherapeutic guidelines;

11. (amend. – SG, 26/19, in force from 01.04.2019) draw up opinions or develop proposals on issues, related to the specialized activity of the Directorate;
12. (amend. – SG, 26/19, in force from 01.04.2019) give opinions on draft legal acts, related to the specialized activity of the Directorate;
13. (new – SG, 26/19, in force from 01.04.2019) support the process of studying the results of the implementation of the normative acts, related to the specialized activity of the Directorate and, if necessary, make proposals for their improvement;
14. (new – SG, 26/19, in force from 01.04.2019) perform legal representation in the areas of activity of the Directorate and provide information to the Directorate of Administrative-Legal Services and Financial Activities on the progress of cases;
15. (former item 13 – SG, 26/19, in force from 01.04.2019) prepare replies and opinions on letters, requests and proposals to the National Council;
16. (former item 14 – SG, 26/19, in force from 01.04.2019) examine signals and complaints, related to the activities of the Directorate;
17. (former item 15 – SG, 26/19, in force from 01.04.2019) draw up proposals for improvement of legal acts, that have a bearing on the prices of medicinal products and their inclusion in the Positive Medicinal List;
18. (former item 16 – SG, 26/19, in force from 01.04.2019) carry out other activities, arising from the decisions of the National Council and from the orders of the Chairperson and the Chief Secretary.

Art. 22. Analytical Activities and Control Directorate shall:

1. perform economic evaluation, collect, analyze and provide to the National Council information on the prices of medicinal products in the Member States, examine the received applications for approval of the price/fixed price, analyze the prices, indicated therein, verifying the information on the prices of medicinal products in the Member States;
2. on the basis of the verification, carried out under item 1, draw up opinions to the National Council on the formation of the manufacturer's price, in accordance with the requirements of the Ordinance under Art. 261a, Para. 5 of the AMPHM;
3. (suppl. – SG, 28/21) prepare opinions and develop proposals for decisions on issues, related to the regulation of prices and reimbursement of medicinal products and carry out coordination and interaction with the competent authorities of other Member States on issues of pricing of medicinal products;
4. maintain an information database, where information on the prices of medicinal products in the Member States of the European Union is collected and stored;
5. (amend. – SG, 26/19, in force from 01.04.2019) maintain the registers of the National Council;
6. prepare replies and opinions to letters, requests and proposals to the National Council;
7. examine signals and complaints, related to the activities of the Directorate;
8. (amend. – SG, 26/19, in force from 01.04.2019) perform inspections, regarding the compliance with the requirements of Chapter Twelve of the AMPHM and the Ordinance, under Art. 261a, Para. 5 of the AMPHM;
9. (new – SG, 26/19, in force from 01.04.2019) carry out verification of the prices of the manufacturer of medicinal products in the database under the EURIPID Collaboration (Collaboration Agreement on Pricing and Reimbursement of Medicinal Products);
10. (new – SG, 26/19, in force from 01.04.2019) shall update the PML in accordance with the requirements of the Ordinance under Art. 261a, Para. 5 of the AMPHM;

11. (new – SG, 26/19, in force from 01.04.2019) collect and store the information from the medical establishments in relation to monitoring the effect of the therapy of medicinal products;

12. (former item 9 – SG, 26/19, in force from 01.04.2019) carry out thematic and counter-checks together with other control bodies;

13. (former item 10 – SG, 26/19, in force from 01.04.2019) draw up reports on the deficiencies and weaknesses of the supervised entities and propose to the National Council measures for their elimination;

14. (former item 11 – SG, 26/19, in force from 01.04.2019, amend. – SG, 28/21) draw up acts for violations of the AMPHM;

15. (former item 12 – SG, 26/19, in force from 01.04.2019) perform other activities, arising from the decisions of the National Council and from the orders of the Chairperson and the Chief Secretary.

Chapter six.

ORGANISATION OF THE OPERATION OF THE NATIONAL COUNCIL ADMINISTRATION

Art. 23. (Amend. – SG, 26/19, in force from 01.04.2019) (1) All documents, received at the National Council shall be registered with a unique register number in the AIS by the Directorate of Administrative and Legal Services and Financial Activities.

(2) On registration of the documents, a check shall be made for the existence of all the materials, referred therein and an official file shall be established.

(3) The Chairperson of the National Council and the Chief Secretary shall assign the official files, except those, opened in respect of administrative procedures requested, by resolution to the heads of the administrative units concerned. The resolution shall contain instructions, a time limit for production, a date and a signature.

(4) Heads of administrative units shall, by resolution, entrust the preparation of the official files, referred to in Para. 3 to a designated employee.

(5) Requests and additions to the administrative services, received on paper or electronically, shall be directed by the clerk's office of the relevant specialized directorate.

Art. 24. (Amend. – SG, 26/19, in force from 01.04.2019) All reports, related to abuse of power and corruption shall be assigned to the Chief Secretary, investigated by him and reported to the Chairperson of the National Council.

Art. 24a. (New – SG, 26/19, in force from 01.04.2019) The procedure for the internal circulation of electronic and paper documents and the archiving of official files shall be determined by internal rules, approved by the Chairperson of the National Council.

Art. 25. In carrying out their functions and specific tasks, the administrative units shall prepare opinions, reports, memos, analyses, programmes, concepts, positions, information, draft decisions on specific issues, internal acts, draft regulations and other documents

Art. 26. The administrative units shall interact directly on matters of mixed competence, with the lead Directorate, summarizing the final opinion.

Art. 27. Coordination and efficiency in activities, concerning two or more Directorates shall be ensured by observing the following procedure of operation:

1. overall coordination:

a) a resolution of the Chairperson, the Chief Secretary and the Director of the Directorate shall indicate on the files the lead unit, the specific tasks to be carried out and instructions for work, as well as the deadline for completion;

b) the lead unit, identified in the first place in the resolution, shall be the main executor of the assigned task and the main coordinator, who shall ensure the necessary coordination between the units; the responsible units shall send to the lead unit their opinion on matters of joint competence;

c) documents, drawn up by two or more units shall be coordinated by their heads;

2. subordination - heads of units report to the Chairperson and the Chief Secretary matters within their competence and on the performance of the tasks, assigned to them;

3. mutual information:

a) analytical reports, information, memos and other general material shall be made available to the administrative units concerned;

b) administrative units, which have received information and material within the competence of other units shall communicate this to those concerned as appropriate;

4. control the performance:

a) the general supervision of the implementation of the tasks assigned shall be carried out by the Chief Secretary;

(b) The heads of the administrative units of the National Council shall exercise overall control over the activities of the unit and over the performance of the tasks, arising from their functional competence.

Art. 28. Units, which have received files with a resolution on matters not within their remit shall forward them to the unit responsible and note this in the document management system.

Art. 29. (Repealed – SG, 26/19, in force from 01.04.2019).

Art. 30. (1) The working hours of National Council employees shall be 8 hours per day on weekdays with a 30-minute lunch break between 12.00 and 14.00. Hours of work may be worked from 7.30am to 6.30pm with a period of compulsory attendance from 10.00am to 4.00pm.

(2) The Chairperson shall, by an order, make arrangements for the introduction of variable hours of work and for the recording of employees' hours of work.

Art. 30a. (New – SG, 26/19, in force from 01.04.2019) For the performance of their duties, the Chairperson and the members of the National Council shall be entitled to cash for representative clothing for each calendar year in the amount of up to two minimum wages for each calendar year, the funds being provided from the budget of the Council. The individual amount shall be determined by an order of the Chairperson of the National Council.

Art. 31. (1) Users of administrative services and persons, submitting written proposals and signals under the Administrative Procedure Code shall be served during working hours.

(2) (Amend. – SG, 28/21) The reception of citizens and representatives of organizations for hearing their oral proposals and signals shall be within the working hours of the National Council.

Art. 32. In order to ensure the continuity of the process of dealing with users of administrative services, the Chief Secretary may, by an order, fix working hours other, than those, generally laid down for staff, carrying out administrative service activities.

Art. 33. (Repealed – SG, 26/19, in force from 01.04.2019).

Concluding Provisions

Paragraph single. The Rules shall be adopted pursuant to Art. 258, Para. 5 of the AMPHM and Art. 51 of the Administration Act.

Concluding Provisions

TO DECREE NO 53 OF 11 MARCH 2014, ADOPTING THE RULES OF PROCEDURE OF THE MEDICAL AUDIT EXECUTIVE AGENCY

(PUBL. - SG, 24/14)

§ 6. Within one month from the entry into force of the Decree, the Minister of Health, the Executive Director of the Executive Agency for Medicines, the Executive Director of the Executive Agency "Medical Audit", the Chairperson of the National Council for Pricing and Reimbursement of Medicinal Products, the Director of the National Centre for Infectious and Parasitic Diseases, the Director of the National Centre for Public Health and Analyses and the Director of the National Centre for Radiobiology and Radiation Protection shall approve the job descriptions of the employees of the structures, headed by them.

Concluding Provisions

TO DECREE NO 315 OF 3 OCTOBER 2014, AMENDING AND SUPPLEMENTING THE RULES ON THE CONDITIONS AND PROCEDURE FOR THE WORK OF THE TRANSPARENCY COMMISSION UNDER THE AMPHM, ADOPTED BY THE COUNCIL OF MINISTERS DECREE NO 300, 2007

(PUBL. – 84/14, IN FORCE FROM 10.10.2014)

§ 10. The Decree shall enter into force on the day of its promulgation in the State Gazette.

Concluding Provisions
TO DECREE NO 67 OF 23 MARCH 2015 ON THE ADOPTION OF THE
RULES OF PROCEDURE OF THE MINISTRY OF HEALTH AND THE
RULES OF PROCEDURE OF THE MEDICAL AUDIT EXECUTIVE
AGENCY

(PUBL. – 23/15, IN FORCE FROM 27.03.2015)

§ 6. The Decree shall enter into force on the day of its promulgation in the State Gazette.

Transitional and Concluding Provisions
TO DECREE NO 56 OF 28 MARCH 2019, AMENDING AND
SUPPLEMENTING NORMATIVE ACTS OF THE COUNCIL OF
MINISTERS

(PUBL. – SG, 26/19, IN FORCE FROM 01.04.2019)

§ 4. (1) The procedures for health technology assessment of medicinal products, not completed by 1 April 2019 shall be completed by the National Council for the Pricing and Reimbursement of Medicinal Products in accordance with the provisions of these Rules.

(2) An authorization holder, who wishes the proceedings, referred to in Para. 1 to be completed as a health technology assessment procedure or the inclusion of a medicinal product, belonging to a new international non-proprietary name in the Positive Medicinal List, shall submit an application to the National Council for Pricing and Reimbursement of Medicinal Products by 20 April 2019.

(3) In the event that, within the time limit, referred to in Para. 2, the respective marketing authorization holder fails to submit an application to the National Council for Pricing and Reimbursement of Medicinal Products, the health technology assessment procedure initiated shall be terminated.

(4) The procedures, initiated at the time of entry into force of this Decree for inclusion in the PML of medicinal products, belonging to a new international non-proprietary name, for which health technology assessment reports, approved by the Director of the National Centre for Public Health and Analyses have been submitted, shall be completed under the terms and conditions of this Decree, without a new health technology assessment and without charging fees for the health technology assessment.

(5) By 10 April 2019, the Director of the National Centre for Public Health and Analyses shall submit to the National Council for Pricing and Reimbursement of Medicinal Products, by means of a handover and acceptance protocol, the applications and documents, submitted for the procedures under Para. 1, as well as the archive of the completed procedures.

§ 5. (1) Within one month of the entry into force of this Decree, hospitals already designated to monitor the effect of drug therapy shall ensure, that their hospital information system is compatible with the Council's information system.

(2) After the expiry of the period, referred to in Para. 1, the medical establishments, referred to in Para. 1 shall provide the Council, through its hospital information system, with data on the medicinal products, for which the effect of therapy has been monitored.

§ 6. (1) By 31 December 2020, the National Council on Prices and Reimbursement shall carry out an official verification of any changes in the approved marginal prices of medicinal products, referred to in Art. 261a, Para. 2 of the AMPHM. The verification shall be carried out in the order of the last approved maximum price of medicinal products.

(2) Where, on the basis of the verification, referred to in Para. 1 it is established, that there has been a change in the respective approved marginal price of a medicinal product, the Council shall ex officio bring it into compliance with the requirements of Art. 10 of the Ordinance on the Regulation and Registration of the Prices of Medicinal Products.

(3) The Council shall notify the marketing authorization holder of the initiation of the administrative proceedings, referred to in Para. 2.

(4) In order to carry out the official check under Para. 1, the holders of use authorizations shall not be liable to pay a state fee.

§ 7. Proceedings, initiated and pending at the entry into force of this Decree for the preparation of a health technology assessment of medicinal products shall be subject to the payment of fees in the amounts, set out in the Tariff of Fees to be collected under the AMPHM.

§ 8. (1) The period, referred to in § 1, item 42, letter "a", subletters "aa" and "bb", letter "c", subletters "aa" and "bb" shall start to run as from 1 April 2019.

(2) Declarations, submitted pursuant to Art. 43 of the Ordinance on the Conditions, Rules and Procedures for the Regulation and Registration of the Prices of Medicinal Products by 1 April 2019 shall be examined by the National Council for Prices and Reimbursement of Medicinal Products in the previous manner.

§ 9. Within one month of the entry into force of this Decree, the Chairperson of the National Council for the Pricing and Reimbursement of Medicinal Products shall approve the job description of the employees of the Council.

§ 10. The Decree shall enter into force on 1 April 2019.

Annex to Art. 16, Para. 3

(Amend. – SG, 24/14, amend. – SG, 84/14, in force from 10.10.2014, amend. – SG, 23/15, in force as from 27.03.2015, amend. – SG, 26/19, in force from 01.04.2019)

Number of staff of the National Council for Pricing and Reimbursement of Medicinal Products and its administration - 44

Chairperson and members of the National Council on prices and reimbursement of medicinal products 7

Administration	37
included:	
Chief Secretary	1
General administration	9
included:	
Administrative, Legal and Financial Directorate	9
Specialized administration	27
included:	
Directorate for Regime Management and Health Technology Assessment	15
Analytical Activities and Control Directorate	12