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English Translation

GOVERNMENT OF THE RUSSIAN FEDERATION

ROADMAP FOR DEVELOPMENT OF COMPETITION IN HEALTHCARE

January 12, 2018, No. 9-r

Moscow

http://static.government.ru/media/files/vyoWQD6EZYQkBaqKfKFKAPZqggtmcHDH.pdf

Last Accessed: 02/14/2018

ПРАВИТЕЛЬСТВО РОССИЙСКОЙ ФЕДЕРАЦИИ
Р А С П О Р Я Ж Е Н И Е
от 12 января 2018 г. № 9-р
МОСКВА

1. Утвердить прилагаемый план мероприятий ("дорожную карту") "Развитие конкуренции в здравоохранении" (далее - план).

2. Реализация мероприятий, предусмотренных планом, осуществляется заинтересованными федеральными органами исполнительной власти в рамках установленной Правительством Российской Федерации предельной численности работников и бюджетных ассигнований, предусмотренных указанным федеральным органам исполнительной власти в федеральном бюджете на руководство и управление в сфере установленных функций

3. Руководителям федеральных органов исполнительной власти, ответственных за реализацию плана:

обеспечить реализацию плана;

представлять ежеквартально, до 5-го числа месяца, следующего за отчетным кварталом, в ФАС России информацию о ходе реализации плана.

GOVERNMENT OF THE
RUSSIAN FEDERATION
O R D E R
January 12, 2018, No. 9-r
MOSCOW

1. To ratify the attached plan of action (“Roadmap”), “Development of Competition in Healthcare” (“the Plan”).

2. Realization of measures called for by the Plan shall be carried out by responsible federal authorities in a framework established by the Government of the Russian Federation with designated agencies and budgetary allocations called for by the designated federal agency in the federal budget for leadership and management in the sphere of its designated functions.

3. The directors of the federal agencies responsible for implementation of the Plan shall:

assure that the Plan is carried out;

submit quarterly reports, prior to the 5th day of the month following the accounting period, to the FAS with information about progress on implementation of the Plan.

4. ФАС России:

обеспечить мониторинг и контроль реализации плана;

представлять ежеквартально, до 25-го числа месяца, следующего за отчетным кварталом, в Правительство Российской Федерации информацию о ходе реализации плана.

Председатель Правительства Российской Федерации
Д. Медведев

4. The FAS shall:

be responsible for monitoring and supervising the implementation of the Plan;

submit quarterly reports, prior to the 25th day of the month following the accounting period, to the Government of the Russian Federation, with information about progress on implementation of the plan.

Chairman of the Government of the Russian Federation
D. Medvedev

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APPROVED
By Order No. 9-r of the Government of the Russian Federation
January 12, 2018

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Measure	Type	Expected Result	Date	Dept.
I. Market for Pharmaceutical Products				
1. State Registration of Pharmaceutical Products				
Establishment of administrative penalties for producers of biotechnological and orphan drugs who fail to submit samples for the conduct of clinical investigations within a period of four years from the date of state registration	Federal Law	Expedited marketing of generic pharmaceuticals and access of patients to innovative drugs	Sept. 2018	Ministry of Health; Ministry of Industry & Trade; FAS
Establishment of administrative penalties for producers of biotechnological and orphan drugs for violation of price controls on pharmaceutical products on the list of lifesaving and essential medicines	Federal Law	Expedited marketing of generic pharmaceuticals and access of patients to innovative drugs	Sept. 2018	Ministry of Health; Ministry of Industry & Trade; FAS
Development of a mechanism of access to the Russian market for innovative drugs going through clinical investigations and registered in the European Union, the United States of America and Japan, including an inscription in the labeling that the medicine has not undergone clinical investigation on the territory of the Russian Federation	Federal Law	Expedited marketing of generic pharmaceuticals and access of patients to innovative drugs	Jan. 2019	Ministry of Health; Ministry of Industry & Trade; FAS

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Measure	Type	Expected Result	Date	Dept.
2. Interchangeability of Pharmaceutical Products				
Establishment of list of reference drugs		Submission of list of reference drugs to FAS; publication of list on websites of Ministry of Health and FAS to provide developers of generic drugs with disclosure of information about reference drugs for state registration of generic drugs; reduction of examination periods for applications by drug manufacturers for registration of maximum mark-ups on medicines on list of lifesaving and essential medicines	June 2018	Ministry of Health
Establishment of administrative penalties for pharmaceutical producers who failure to provide full and accurate information about the contents and characteristics of medicines in labeling and instructions	Federal Law	Creation of conditions for competition among pharmaceutical products; ensuring the safety of pharmaceutical products	Sept. 2018	Ministry of Health; FAS
Establishment of model instructions for the use of interchangeable pharmaceutical products	Order by Ministry of Health	Elimination of unjustified variations in instructions for interchangeable pharmaceuticals having a single international nonproprietary name; creation of conditions for competition among pharmaceutical producers	Jan. 2019	Ministry of Health; Ministry of Industry and Trade; FAS
Establishment of equivalent therapeutic doses for medicines registered prior to approval of Order No. 538n of the Ministry of Health dated July 27, 2016 “On the Approval of the List of Names of Medicinal Forms of Pharmaceutical Products for Medical Use.”[1]	Order of Ministry of Health	Reduction of limitations on competition among producers of pharmaceutical products registered prior to approval of the List of Names of Medicinal Forms of Pharmaceutical Products for Medical Use	Dec. 2018	Ministry of Health; Ministry of Industry and Trade; FAS

[1] On August 17, 2016, the Russian Ministry of Justice registered Order No. 538n of the Ministry of Health dated July 27, 2016 "On the Approval of the List of Names of Medicinal Forms of Pharmaceutical Products for Medical Use." The name of the dosage form includes a

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Measure	Type	Expected Result	Date	Dept.
Examination of documents in registration dossiers of imported pharmaceutical products for conformance with the dossiers for identical products registered abroad and conformance with dossiers on reference and generic drugs registered in the Russian Federation	Report to Government of the Russian Federation	Creation of conditions for competition among pharmaceutical producers	Aug. 2019	Ministry of Health; Ministry of Economic Development; FAS
Establishment of a commission in the Ministry of Health with responsibility for creation of a list of lifesaving and essential medicines considering the availability of equivalent applications	Decree by Government of the Russian Federation	Creation of equal conditions for producers of interchangeable pharmaceutical products; prevention of unjustified inclusion of pharmaceuticals in the list of lifesaving and essential medicines	Aug. 2018	Ministry of Health; Ministry of Economic Development; FAS
Establishment of professional responsibility of medical workers for violation of Law on Circulation of Medicines in the public health sector	Report to Government of the Russian Federation	Elimination of disparity in responsibility for the level of public danger in violations of Russian law on Circulation of Medicines; elimination of limitations in competition in the sphere of circulation of interchangeable pharmaceutical products; increase of access to pharmaceutical products by patients based on right to choose pharmaceuticals at the most reasonable price.	Sept. 2018	FAS; Ministry of Health; Federal Service for Surveillance in Healthcare and Social Development

basic element designating an independent, homogeneous group of forms (tablets, capsules, solution, ointment and other forms) that can be supplemented by one or more additional elements characterizing the properties of the dosage form (type of modified release of active ingredients (sustained release capsules)), sign of readiness for use (powder for solution for injection), administration method (liquid for inhalation), route of administration (solution for nutritional injections), features of manufacturing technology (film-coated tablets), dose-sharing (nasal dosed spray), age group of patients (rectal suppositories for children), destination or area of application (dental paste). The order is applied to the names of medicinal forms of medicinal products, applications for state registration of which are submitted to the Ministry of Health after the entry into force of this order. https://pharmvestnik.ru/publs/lenta/v-rossii/utverzhden-perechenj-naimenovanij-lekarstvennyx-form-lekarstv.html.

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Measure	Type	Expected Result	Date	Dept.
Notice to the medical community and patients about interchangeable pharmaceutical products	Report to Government of the Russian Federation	Education of the public and medical workers about the availability of less expensive analogs to expensive pharmaceuticals; creation of sustainable demand for pharmaceuticals in the lower income segment; preventing lower priced pharmaceuticals from "shaking out" of the market	Sept. 2018	Ministry of Health; Ministry of Education and Science; Ministry of Communications and Mass Media; Ministry of Industry and Trade; Federal Service for Surveillance in Healthcare;[2] FAS
Introduction of requirements for pharmacy organizations to first offer purchasers the least expensive drugs and notify purchasers regarding the availability less expensive analogs and their prices	Order by Ministry of Health	Increase of accessibility in terms of price and assortment by means of preventing lower priced pharmaceuticals from "shaking out" of the market	Nov. 2018	Ministry of Health; FAS
Determine feasibility of amendments to Article 18 of Federal law "On the Circulation of Medicines" relating to the establishment of a prohibition against state registration of generic drugs in dosages differing from the dosages of reference drugs, as well as state registration of generic drugs, instructions for medical use of which differ from the instructions for medical use of reference drugs	Report to Government of the Russian Federation	Elimination of opportunity for registration of medicines in therapeutically unjustified dosages; prohibition against unfair use of information in instructions for medical use of pharmaceuticals at the time of purchase.	Nov. 2018	Ministry of Health; FAS

[2] Ed. Note: www.roszdravnadzor.ru/en.

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Measure	Type	Expected Result	Date	Dept.
Establishment of procedure for changes in instructions for medical use of drugs registered in the framework of a single international nonproprietary name, in particular mandatory changes in instructions for medical use of drugs involving counter indications and side effects; resolve issues relating to administrative penalties on holders or owners of marketing authorizations for failure to fulfill designated requirements	Federal Law	Elimination of unjustified distinctions in instructions for medical use of drugs having one international nonproprietary name	Oct. 2018	Ministry of Health; FAS
Establishment of procedure for the formulation of lists of drugs, designated dosage forms and applications	Decree of Government of the Russian Federation	Creation of equal conditions for circulation of equivalent dosage forms of drugs	July 2018	Ministry of Health; Ministry of Industry and Trade; FAS

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Measure	Type	Expected Result	Date	Dept.
3. Establishment of Mechanism for Regulation of Prices for Pharmaceutical Products on the List of Lifesaving and Essential Medicines				
Implementation of amendments to Federal Law "On Circulation of Medicines" and rules for establishment of maximum mark-ups of wholesale and retail prices by producers of pharmaceutical products on the list of lifesaving and essential medicines, for subjects of the Russian Federation confirmed by Decree No. 865 of the Government of the Russian Federation dated October 29, 2010, "On government regulation of prices for pharmaceutical products included on the list of lifesaving and essential medicines," calling for the setting of retail prices on drugs included on the list of lifesaving and essential medicines, depending on the legal status of the taxpayer	Federal Law, Decree of Government of the Russian Federation	Elimination of contradictions in legislation regarding the calculation of selling prices for medicines included in the list of lifesaving and essential medicines, depending on the legal status of the taxpayer	Dec. 2018	FAS; Ministry of Health; Ministry of Economic Development; Ministry of Industry and Trade; Ministry of Finance

Measure	Type	Expected Result	Date	Dept.
Establishment of procedure for state registration of maximum mark-ups on prices for drugs on the list of lifesaving and essential medicines	Federal Law; Decree by Government of the Russian Federation	Elimination of discrimination between domestic and foreign drug producers; increase in informational character and accuracy of government register of maximum mark-ups on prices of medicines on list of lifesaving and essential medics; prevention of opportunity for linkage of marginal mark-ups to prices of drugs not in circulation; providing of verified data to government and municipal purchasers as necessary for calculation of initial (and maximum) prices of state and municipal contracts; establishment of possibility for retraction or reexamination of decisions on registration of maximum mark-ups resulting from mistakes by responsible federal authorities; elimination of risks of substantial increase in budgetary expenses in the inclusion of new drugs in the list of lifesaving an essential medicines	Feb. 2019	Ministry of Health; Ministry of Economic Development; Ministry of Industry and Trade; Ministry of Finance; FAS
4. Regulation of State and Municipal Procurement of Medicines				
Development of model contracts calling for identical technical tasks by category of drug	Order by Ministry of Health	Elimination of limitations on competition in state and municipal purchases; creation of equal conditions for suppliers of drugs at auction	April 2018	Ministry of Health; Ministry of Finance; Ministry of Industry and Trade; FAS

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Measure	Type	Expected Result	Date	Dept.
Establishment of criteria for market conditions permitting sole-source supply of pharmaceutical products; establishment of procedure for selection of contractor for supply of drugs with the aim of developing drafts of corresponding regulations by the President of the Russian Federation and the Government of the Russian Federation for determination of sole source drug suppliers	Federal Law, Decree by Government of the Russian Federation	Creation of mechanism for decisions by the President of the Russian Federation and the Government of the Russian Federation on the determination of sole source suppliers of drugs based on transparent procedures and objective criteria; increase in the efficacy of the budgetary expenses	Feb. 2019	Ministry of Industry and Trade; Ministry of Finance; Ministry of Health; FAS
Establishment of opportunity for sole- source supply only in connection with medicines lacking an analog on the territory of the Russian Federation	Federal Law; Decree by Government of the Russian Federation	Prevention of unjustified limitations in competition in generic medicines; increase in efficacy of budgetary expenses	Feb. 2019	Ministry of Industry and Trade; Ministry of Finance; Ministry of Health; FAS
Establishment of limitations on the execution of long-term government contracts for the supply of medicines, including the establishment of an opportunity for execution of long-term government contracts only for medicines protected by patents and subject to a meaningful reduction of price on such medicines; limitation on the period of validity of long-term government contracts to the term of the patent on the medicine or the date of release onto the market of another medicine having the same indications and use	Federal Law	Elimination of unjustified limitation on competition in the appearance of generic medicines; increase of efficacy of budgetary expenses; stimulation of release onto the market of generic medicines, as well as other medicines having the same indications; lowering of prices for medicines not having analogs, on account of guaranteed volumes of production; reduction of costs of state purchasers tied to procurement of medicines	June 2019	FAS; Ministry of Finance; Ministry of Health; Ministry of Industry and Trade

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Measure	Type	Expected Result	Date	Dept.
Establishment of particulars in the description of medicines for execution of procurement, including medicinal forms and dosages of medicines; establishment of prohibition on combining in one lot services for supply, storage and release of medicines; establishment of requirements for indicating in documentation on the procurement of the remaining period of validity of medicines, expressed in the designated period (for example, in years, months, days), during which the medicines preserve their efficacy for their designated purpose	Decree by Government of the Russian Federation	Elimination of limitations and suppression of competition by state and municipal purchasers; increase in quantity of participants of procurement; increase in efficacy of budgetary expenses; creation of equal conditions for suppliers of interchangeable drugs having distinctions in nominal periods of validity; prevention of designation of remaining period of validity in percentages	Sept. 2018	FAS; Ministry of Finance; Ministry of Health; Ministry of Industry and Trade
Establishment of opportunity for determination of country of origin of medicines based on marketing authorization without the need for receipt of Certificate ST-1	Federal Law; Decree by Government of the Russian Federation	Elimination of excessive administrative barriers; lowering of restraints on suppliers of medicines participating in public procurement; lowering of prices on drugs	Oct. 2018	Ministry of Industry and Trade; Ministry of Economic Development; Ministry of Health; FAS
5. Enactment of legal regulation in the sphere of intellectual property protection				
Clarification of conditions for patentability of inventions in connection with patenting of any new property or new application of a known existing substance of a drug	Report to Government of the Russian Federation	Determination of questions relating tithe patentability of modifications to existing medicines, including new indications, therapeutic methods, combinations of existing substances, medicinal forms, and means of production	Sept. 2018	Ministry of Economic Development; Ministry of Education and Science; Ministry of Industry and Trade; Rospatent; FAS

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Measure	Type	Expected Result	Date	Dept.
Establishment of periods of examination of disputes relating to the protection of intellectual property	Order of Ministry of Education and Science	Change in the procedure for exemption of disputes connected to protection of intellectual property; expediting of release onto the market of generic and biosimilar drugs	Aug. 2018	Ministry of Education and Science; Rospatent; FAS
Development of procedures as contemplated by Article 1360 of the Civil Code for issuance of permission to use inventions, utility models and industrial designs of pharmaceutical substances without the agreement of the patent holder	Federal Law; Decree by Government of the Russian Federation	Establishment of conditions for implementation of Article 1360 of the Civil Code for the purpose of lowering prices on expensive drugs protected by patent and necessary for combatting epidemics threatening national security	Dec. 2018	FAS; Ministry of Health; Ministry of Industry and Trade; Ministry of Education and Science; Rospatent

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Measure	Type	Expected Result	Date	Dept.
6. Development of competition among pharmacy organizations				
Establishment of rules for long-distance trade in medicines by pharmacy organizations, including a mechanism for the limitation of access to websites not in compliance with designated rules	Federal Law; Decree by Government of the Russian Federation	Creation of equal conditions for functioning of pharmacy organizations, suppression of trade in counterfeit pharmaceuticals and inferior medicines sold on the Internet; timely blocking of Internet sites not in compliance with rules for long-distance trade	Nov. 2018	Ministry of Health; Ministry of Telecom-munications and Mass Media; Ministry of Economic Development; Ministry of Agriculture; Federal Service for Surveillance in Healthcare; Federal Service for Supervision of Communications, Information Technology and Mass Media; FAS
Development of administrative procedure for exercise of control over long-distance trade in medicines	Order of Ministry of Health	Regulation of procedure and periods of execution by authorized federal executive government authority of state functions for the control over distance trade in medicines	July 2019	Ministry of Health; Federal Service for Surveillance in Healthcare
Measures to support pharmacy organizations of various forms of ownership in municipalities of up to 100,000 population for the purpose of providing related recommendations to subjects of the Russian Federation	Report to Government of the Russian Federation	Development of competition among pharmacy organizations in municipalities of up to 100,000 population; improvement in physical access to medicines by under populated and remote population centers	Nov. 2019	FAS; Ministry of Economic Development; Ministry of Health

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Measure	Type	Expected Result	Date	Dept.
II. Markets for Medical Devices				
7. Legal regulation in the circulation in medical devices				
Establishment of a procedure for determination of interchangeability of medical devices, including consumable materials	Decree by Government of the Russian Federation	Creation of conditions for development of competition among producers of medical devices	Nov. 2018	Ministry of Health; Ministry of Industry and Trade; Federal Service for Surveillance in Healthcare; FAS
Development of administrative procedure for determination of interchangeability of medical devices	Order by Ministry of Health	Regulation of procedure and periods for execution by federal agencies for determination of interchangeability of medical devices	March 2019	Ministry of Health; Ministry of Industry and Trade; Federal Service for Surveillance in Healthcare
Determination of characteristics of medical devices of the "open" and "closed" types, as well as establishment of obligations of state and municipal purchasers to procure medical devices of the "open" type	Federal Law; Decree by Government of the Russian Federation	Creation of conditions for development of competition in the market for medical devices	Jan. 2019	Ministry of Finance; Ministry of Health; FAS
Requirements for inclusion of information about the period of use, including guarantee of usefulness, cost of technical service and repair of medical devices, as well as the cost of training of medical workers of rules of use and utilization of medical devices, in technical documentation for medical devices	Decree by Government of the Russian Federation	Creation of conditions for development of competition in the market for technical servicing of medical devices	March 2019	Ministry of Health; Ministry of Economic Development; FAS

Measure	Type	Expected Result	Date	Dept.
Reexamination procedures for the setting of payments and examination of quality, efficacy and safety of medical devices, eliminating arbitrary decisions by the executive agency especially the determination of place of conduct, quantity and character of investigations of medical devices in connection with government registration; establishment of procedure for extra-judicial challenge to results of examination of quality, efficacy and safety of medical devices	Federal Law	Unification of procedure for government registration of medical devices; elimination of corruption-related factors	Sept. 2018	Ministry of Health; Ministry of Industry and Trade; Ministry of Economic Development; Federal Service for Surveillance in Healthcare; FAS
Establishment of requirements for servicing of medical devices; providing information to purchasers for the functioning of medical devices, including the providing of keys, access passwords, programs and other information necessary for the assembly, operation, application, exploitation, including technical servicing of medical devices; prohibition against the unjustified limitation by producers of medical equipment on the possibility for use of consumable materials and reagents of other producers; placement on official website of the Federal Service for Surveillance in Healthcare of documentation for every medical device; establishment of requirements for producers of medical devices on nondiscriminatory basis to conduct training of persons engaged in technical servicing of medical devices	Federal Law	Creation of conditions for development of competition in the markets for medical devices, consumable materials, and technical servicing	Mar. 2019	Ministry of Health; Ministry of Industry and Trade; Federal Service for Surveillance in Healthcare; FAS
8. State and municipal procurement of medical devices				
Development of model contracts calling for unified technical requirements for separate categories of medical devices	Order by Ministry of Health	Elimination of limitations and suppression of competition by state and municipal purchasers; creation of equal conditions for suppliers of medical devices at auction	April 2019	Ministry of Health; Ministry of Finance; Ministry of Industry and Trade; FAS

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Preparation of proposals for the implementation of amendments to the list of goods and services in which the purchaser is obligated to conduct an auction in electronic format (electronic auction), approved by Order No. 471-r of the Government of the Russian Federation dated march 21, 2016, in particular the inclusion in the list of all medical devices without exception	Report to Government of the Russian Federation	Elimination of the opportunity for arbitrary actions by state and municipal purchasers in ranking and the unjustified valuations of applications for the holding of tenders	June 2018	Ministry of Health; Ministry of Finance; FAS
Establishment of requirements for participants of state and municipal procurement of medical devices the utilization of which requires the use of consumable materials and identification in technical documentation of the producer of medical device requirements for consumable materials, providing requisite utilization of medical devices, as well as establishment of particulars for purchases by state and municipal purchasers of medical devices of the "open" type	Decree by Government of the Russian Federation	Creation of conditions of economic development in the market for technical servicing of medical devices	Nov. 2018	Ministry of Finance; Ministry of Health; FAS
Establishment of requirements for the inclusion in documentation for the procurement of medical devices of information about the expiration date of medical devices (for example, in years, months, and days),	Decree by Government of the Russian Federation	Creation of equal conditions for suppliers of interchangeable medical devices having various nominal periods of validity; prohibition against indication of remaining period of validity of medical devices in percentages; increase in the quantity of participants of procurements; increase in effectiveness of budgetary expenses	Oct. 2018	FAS; ministry of Finance; Ministry of Health; Ministry of Industry and Trade
Establishment of requirements for state and municipal purchasers of medical devices to specify the initial (and maximum) price of contract accounting for the acquisition of consumable materials and technical servicing prior to the expiration date	Decree by Government of the Russian Federation	Creation of conditions for development of competition in the markets for technical servicing of medical devices	March 2019	Ministry of Finance; Ministry of Health; FAS

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III. Market for Medical Services				
9. Healthcare legislation, in particular the determination of volumes and types of medical assistance in territorial programs for government guarantees of unpaid medical assistance; annual renewal of government guarantees for unpaid rendering of medical assistance in the implementation of new medical technologies	Federal Law; Decree by Government of the Russian Federation	Fulfillment of citizens' rights to unpaid medical assistance	Feb. 2019	Ministry of Health; Ministry of Economic Development; Federal Service for Surveillance in Healthcare; FAS
10. Amendments to Article 18 of Federal Law "On licensing of different types of activities" and Paragraph 3 of Decree No. 957 of the Government of the Russian Federation dated Nov. 21, 2011, "On the organization of licensing of different types of activities," calling for a change of the procedure for reissuance of a license for the rendering of medical and pharmaceutical activity in connection with new addresses of places of business in the procedure for execution by licensing agencies of a subject of the Russian Federation and attachment to license with indication of new addresses of place of business, without change to the requisites of the license itself or need for presentation of original license to the licensing agency	Federal Law; Decree by Government of the Russian Federation	Removal of unjustified administrative barriers in the reissuance of a license for rendering of medical and pharmaceutical activity; expediting of development of medical and pharmacy organizations in subjects of the Russian Federation	April 2019	Ministry of Economic Development; Ministry of Health; Federal Service for Surveillance in Healthcare; FAS

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11. Approval and implementation of clinical recommendations (treatment protocols)	Orders of the Ministry of Health of the Russian Federation	Increase in quality of medical assistance	Dec. 2019	Ministry of Health
12. Development of proposals for the establishment of conditions under which government (municipal) medical organizations may render paid medical services	Report to Government of the Russian Federation	Creation of equal conditions for the rendering of paid medical services by government, municipal and private medical organizations; prohibition of rendering by government medical organizations of paid medical services which should be rendered in the framework of territorial programs of government guarantees for unpaid rendering to citizens of medical assistance	Nov. 2018	FAS; Ministry of Health
13. Proposals for a mechanism to distribute medical assistance to participants in territorial programs of government guarantees for unpaid rendering to citizens of medical assistance	Report to Government of the Russian Federation	Creation of equal conditions of participation of medical organizations in the system of mandatory medical insurance; prevention of abuses of commissions for the development of territorial programs of mandatory medical insurance for the distribution of volumes of medical assistance by participants of mandatory medical insurance	Nov. 2018	FAS; Ministry of Health; Federal Compulsory Medical Insurance Fund

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	Measure	Type	Expected Result	Date	Dept.
IV. Market for Biologically Active Additives					
14	**Legal regulation of biologically active additives by means of prohibition on government registration of biologically active additives of pharmaceutical substances or products having pharmaceutical substances; prohibition on government registration of identically named or confusingly similar biologically active additives and medicines**		Application to Eurasian Economic Commission for amendments to technical regulations of the Customs Union TR TS 021/2011, 022/2011, with the aim of suppressing the unlawful circulation of biologically active additives and passing-off as to the content and substance of biologically active additives; providing of safety to citizens	Sept. 2018	Federal Service for Surveillance in the Sphere of Consumer Protection and Human Welfare; Ministry of Health; FAS
15.	**Review of all previously registered biologically active additives, identically named or confusingly similar to medicines**		Draft recommendation to the Committee of Eurasian Economic Commission for adoption of decision to withdraw from circulation biologically active additives identically named or confusingly similar to medicines, including biologically active additives registered in countries of the Eurasian Economic Union	Nov. 2021	Federal Service for Surveillance in the Sphere of Consumer Protection and Human Welfare; FAS