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PHILIP MORRIS OPERATIONS A.D. NIŠ

GREY BOOK OF INNOVATION 2.0

Recommendations for improving the conditions for innovative and high-tech entrepreneurship in Serbia 2023 - Summary

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FOREWORD

Ivan Miletić
President of NALED's Fair Competition Alliance
Director External Affairs, South East Europe, Philip Morris International

Dear members and partners,

It is my great honor and pleasure to present you with the second, improved edition of the Grey Book of Innovation. We are pleased as the new publication confirms the continuity in building and improving the conditions for innovative and high-tech entrepreneurship in Serbia by removing the administrative and regulatory obstacles. The second round of Grey Book of Innovation brings 45 recommendations, including 12 new ones, from six areas significant for further development of innovation in Serbia.

We can boast of having line institutions and relevant stakeholders in this field recognize the Grey Book of Innovation as a reference material in their work. This is supported by the fact that we handed out the first circulation of its printed edition in less than a month, but most importantly – that we managed to resolve, partially or fully, nine recommendations, and make progress in another six.

Over the past three years, thanks to StarTech program, we have achieved major successes. As part of the support program to innovative businesses, over three cycles, 82 grants have been awarded to startups and SMEs in the field of mechanical engineering and electronics, food and agriculture, artificial intelligence and biotechnologies. The innovation policy lab contributed to systemic improvement of the business framework for innovators, by encouraging dialogue, initiating analytics-based reforms and coordinating the initiatives of the public, private and civil sector. We have provided support in developing a web portal for freelancers' income reporting and establishing a Viber chatbot informing businesses about available incentives and support programs, while a web portal linking together big and small businesses is currently under development. By taking part in working groups, we contributed to amendments of regulations that enabled detailed defining of startups and business angels, testing of autonomous vehicles and reducing the tax burden. More than 150 accountants and 170 freelancers underwent trainings on tax issues, and StarTech also found its regular slot on national TV through educational series on digital entrepreneurship GOStudy.

Though initially StarTech was meant to last for three years, we are very pleased to announce that our work on strengthening the innovation ecosystem in Serbia is not done yet. Guided by the achieved results, Philip Morris decided to continue its support to innovators in Serbia and maintain similar activities for another three years. The continuation of StarTech project will open up some new important topics, such as the development of technology transfer, and build the potential for stronger cooperation with important innovation ecosystem entities, such as the Bio4 Campus.

It is said that good things are not to be changed – hence, Philip Morris, NALED and StarTech will remain a reliable partner to the Government of Serbia in initiatives for transforming economy and improving the business conditions in Serbia.

INTRODUCTION

The Grey Book of Innovation was designed and modeled based on NALED's most prominent and influential publication – the Grey Book of Regulations that has, over the course of 15 years, become a kind of regulatory bible for decision-makers and public policy creators in our country. Being highly practical and comprehensive, the Grey Book has managed to bring together all segments of the society and encourage them to take part and actively contribute towards achieving a common goal – creating better business environment by eliminating excessive administration. It is the same ambition, but with special focus on high-tech entrepreneurship, that we achieve with the now second edition of the Grey Book of Innovation.

The second edition was also created within a program entirely financed by a private company, Philip Morris in Serbia, supporting innovation and digital transformation of small and medium enterprises – the program StarTech, which aims to transform the traditional economy into a digital and high-tech economy, through direct financial and expert support to businesses, work on improving the conditions to implement innovation, and the promotion of innovators and Serbia as an investment destination.

The Global Innovation Index 2023 ranks Serbia 53rd out of a total of 132 countries, which is a step forward by two positions compared to the previous year. Serbia is one of 19 European countries that climbed the ladder of innovation this year, which testifies to the strong competition in this field. This result stems from the positive performance in terms of the inflow of foreign direct investments (ranked 11th globally per capita), labor productivity (ranked 14th) and the growth of overall R&D expenses by as much as 18.1%. On the other hand, the R&D investments in the private sector remain low (87th), as well as the share of researchers in businesses (65th) and the start-up and scale-up funding (66th). In conclusion, Serbia is facing a systemic challenge in turning fairly good inputs (leap from 55th to 41st position) into good innovation results (drop from 58th to 64th position).

The second edition of the Grey Book of Innovation should help in overcoming this systemic challenge, with 45 concrete recommendations for improving the work conditions for innovators. The key ideas for defining these recommendations were gathered through consultation with startups, researchers, academia and sectorial associations. The process of collecting recommendations and the final curation of the Grey Book of Innovation was coordinated by the members NALED's Innovation Policy Lab and external experts.

The second edition of the Grey Book of Innovation includes 12 new recommendations. The ones that remained unresolved from the previous edition were once again analyzed, and modified where needed. All recommendations are grouped into six areas, as follows:

1. *Innovative entities and support organizations*
2. *Science-to-business cooperation and intellectual property*
3. *Finance and digital assets*
4. *Taxes and customs*
5. *Infrastructure and mobility*
6. *Use of data*

Similar to the previous edition, this year's Grey Book also encompasses a large number of relevant regulations, proposing their amendments – as many as 52. The largest number of recommendations refer to the Law on Personal Income Tax (16%), the Customs Law

(11%) and the Law on the Protection from Non-Ionizing Radiation (8%). As for the ministries, the largest number of recommendations relate to issues under the jurisdiction of the Ministry of Finance and its directorates – in more than 40% of all recommendations. They are followed by the Ministry of Environment Protection (18%), the Ministry of Construction, Transport and Infrastructure (13%), while five recommendations are each addressed to the Ministry of Science, Technological Development and Innovation, the Ministry of Information and Telecommunication and the Ministry of Justice.

Even though all recommendations are highly significant in further encouraging the development of the innovation ecosystem, there are 10 recommendations, whose resolution we find a top priority:

GREY BOOK OF INNOVATION: 10 PRIORITY RECOMMENDATIONS

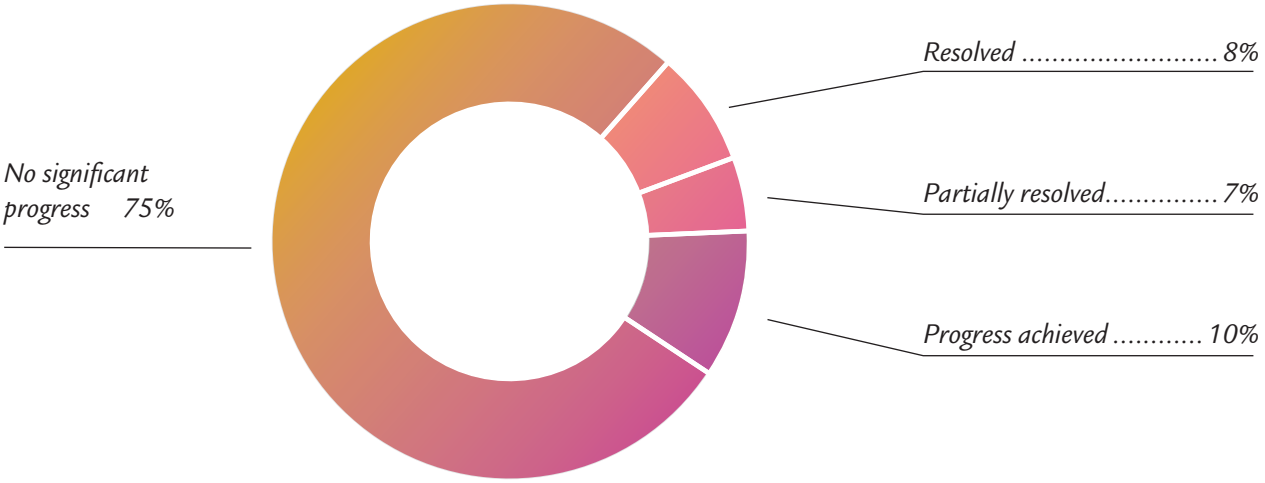
Recommendation number	RECOMMENDATION TITLE	LINE INSTITUTION
2.1	Create the conditions for cooperation between science and businesses through industrial doctorates	Ministry of Science, Technological Development and Innovation
3.4	Ensure that open call conditions for entrepreneurship development programs do not exclude beneficiaries of business incubators and other support organizations	Ministry of Economy, Development Fund of the Republic of Serbia
3.11	Enable and govern the conditions for investments of voluntary pension funds in AIF venture capital	Ministry of Finance, National Bank of Serbia
3.14	Specify the conditions for documenting the costs arising in the creation of digital assets	Ministry of Finance
4.5	Define the concept of a sample of significance for research and development	Ministry of Health, Agency for Medicines and Medical Devices
4.7	Simplify the import of unregistered medical devices for research and development purposes	Ministry of Health, Agency for Medicines and Medical Devices
4.8	Introduce a system of collective permits and notifications for the import and export of biological material	Ministry of Health, Agency for Medicines and Medical Devices
5.1	Abolish arbitrary restrictions at the level of local governments for setting up mobile radio base stations	Ministry of Environment Protection, Ministry of Construction, Transport and Infrastructure, Ministry of Information and Telecommunication
6.1	Enable storage of local government data in the state center for data management and storage and use of cloud services	Ministry of Public Administration and Local Government, Ministry of Information and Telecommunication
6.2	Regulate the conditions for the implementation of telemedicine	Ministry of Health

The same as in previous years, NALED will actively advocate all recommendations and provide support to line institutions in their implementation and monitoring. Like last year, we thank everyone who invested their time and energy to highlight the problems, propose solutions or share how current regulations and their implementation affect their work. We promise to keep working on the implementation of proposed improvements, from the very first day of Grey Book of Innovation publication.

OVERVIEW OF IMPLEMENTED RECOMMENDATIONS FROM THE FIRST EDITION

THE MINISTRY OF SCIENCE, TECHNOLOGICAL DEVELOPMENT AND INNOVATION IS THE MOST AGILE IN LISTENING TO THE NEEDS OF INNOVATORS.

Out of 60 recommendations from the first edition of the Grey Book of Innovation, nine recommendations have been resolved, of which five entirely and four partially, while another six recommendations noted progress towards their implementation.



The Ministry of Education, Science and Technological Development, i.e. currently the Ministry of Science, Technological Development and Innovation, was shown to be the most open to the needs of innovators. With three fully resolved, two partially resolved, and one recommendation with progress noted, it is absolute champion in resolving the recommendations from the first edition of Grey Book of Innovation.

The Rulebook on the Register of national innovation system entities defines in more details the notions of startups and business angels, and determines the condition for their entry into the Register. Upon being registered, innovators can use the funds of the Innovation Fund, while the state gains insight into the current state of the innovation system. It also specifies that 'other innovation infrastructure entities' may include associations, businesses and entrepreneurs whose aim is to support the innovation activities, and the issue of the development, application, and use of reliable and responsible artificial intelligence is regulated by Ethical Guidelines. A training was organized for civil servants on the topic of Partnership for Innovation, and the Ministry initiated work on developing a web portal to connect science, businesses and the state.

MINISTRY OF SCIENCE, TECHNOLOGICAL DEVELOPMENT AND INNOVATION	
Specify the conditions for obtaining the status of innovation entity	Resolved
Specify the definition of business angel in the Law on Innovation Activity	Resolved
Expand the scope of entities that can gain the status of a startup support organization	Resolved
Regulate legally the use of artificial intelligence, especially concerning the implementation of ethical standards	Partially resolved
Strengthen the capacities of public administration for providing support to innovative entities	Partially resolved
Establish online central record of scientific research infrastructure	Progress achieved

The second best rated is the Ministry of Interior. The amendments to the Law on Road Traffic Safety regulated the use of light electric vehicles (scooters) and enabled road testing of autonomous vehicles.

MINISTRY OF INTERIOR	
Introduce regulatory safe test environment for testing autonomous vehicles	Resolved
Legally regulate micro-mobility – the use of electric scooters, bicycles and similar vehicles	Resolved

The third position is held by the Ministry of Construction, Transport and Infrastructure with two partially resolved recommendations. Amendments to the Rulebook on the special type of objects and special type of works that do not require an act from a line authority eased the process of setting up charging stations for electric and hybrid vehicles on public roads, while amendments to the Law on Planning and Construction prescribed that planning documents cannot introduce additional limitations on local government level for setting up radio base stations for mobile telephony.

MINISTRY OF CONSTRUCTION, TRANSPORT AND INFRASTRUCTURE	
Ease the procedure for setting up electric vehicles charging stations	Partially resolved
Abolish arbitrary limits on local government level for setting up radio base stations for mobile telephony	Partially resolved

With a score of 15% of resolved and partially resolved recommendations, the Grey Book of Innovation reached the average fulfillment rate of its "role model", NALED's Grey Book. With the aim of increasing the share of resolved recommendations year by year, NALED will continue to provide support to institutions in the creation, adoption and implementation of reforms towards building a favorable business environment for innovative and high-tech entrepreneurship in Serbia.

10 PRIORITY RECOMMENDATIONS

2.1. CREATE THE CONDITIONS FOR COOPERATION BETWEEN SCIENCE AND BUSINESSES THROUGH INDUSTRIAL DOCTORATES

Ministry of Science, Technological Development and Innovation, Ministry of Economy

PROBLEM DESCRIPTION

One of the most significant global indices in the field of innovation, Global Innovation Index, estimates the university-industry R&D cooperation in Serbia with 44.5 out of 100 points. Additionally, the industry-university relation according to the Knowledge Economy Index is rated with 3.8 out of 10 points. Finally, the Global Competitiveness Index estimates that there is room for strengthening cooperation among multiple stakeholders in the entire region - Bosnia and Herzegovina (31/100), Croatia (32.9/100), North Macedonia (34.2/100), Serbia (42,9/100), Montenegro (48,7/100).

Industrial PhDs are practiced in the leading countries when it comes to innovation, such as Sweden, Germany or Denmark. An industrial doctorate in Sweden stands for a three-year research project realized in cooperation between a public or private company, a PhD student in the same field of industry and a faculty. During the program, the student is employed in the company, while working on the PhD thesis in parallel, on a topic relevant for the company. This way, the universities cooperate with companies that cover the scholarship and research costs for the PhD students.

The findings of focus groups with businesses indicate that companies are in need of various services from the scientific community, including publication of joint research, but they are not familiar with the mechanisms for cooperation.

PROPOSED SOLUTION

We propose the following:

1. Establishing a co-funding program for industrial doctorates by the Ministry of Science, Technological Development and Innovation, that would be intended for companies that seek research publishing, and on the other hand, for PhD students, with the aim of employment where the PhD thesis / research would focus on the needs of the company. We propose that the co-funding be organized in a manner where the Ministry would cover 30% of expenses, while the interested company would account for 70%, with possible co-funding by the faculty or university as well.
2. Adoption of Guidelines for implementing industrial doctorates, that would include the framework for the procedure and the manner of financing PhD studies sourced by businesses, and for governing their mutual rights and obligations, i.e. the principles of cooperation between the company-sponsor, the faculty or another academic institution, and the PhD student-grantee, in line with the purpose of scholarship, the sponsoring company business interests and the long-term need for expertise.

This way, the companies will ensure researchers with competencies needed to perform high-quality research, they will strengthen their relations with academic circles and ensure access to the latest research results, while students will have an opportunity to apply and test their academic knowledge in practice and gain competences for the labor market, while still studying.

Examples from Sweden and Germany show that industrial doctorates are not opposed to the Bologna process principles, which can also be determined based on general descriptors for the qualifications gained after completed third-degree studies.

PROGRESS ACHIEVED

Upon agreement with the Ministry of Science, Technological Development and Innovation, NALED created a proposal of industrial doctorates co-funding program, as well as draft Guidelines for implementing industrial doctorates. NALED is expected to present the proposals to the Ministry in the upcoming period, and the following steps will be determined towards program implementation and Guidelines adoption.

REGULATIONS: Guidelines for implementation of industrial doctorates

3.4. ENSURE THAT OPEN CALL CONDITIONS FOR ENTREPRENEURSHIP DEVELOPMENT PROGRAMS DO NOT EXCLUDE BENEFICIARIES OF BUSINESS INCUBATORS AND OTHER SUPPORT ORGANIZATIONS

Ministry of Economy, Development Fund of the Republic of Serbia

PROBLEM DESCRIPTION

The Ministry of Economy, through the Development Fund of the Republic of Serbia, performs annual programs to encourage entrepreneurship development through financial support in terms of grants for first-time businesses that meet certain requirements, in line with the decree on an annual basis that determines the programs encouraging entrepreneurship development through financial support for first-time businesses and youth, as well as the open call for the implementation of such program.

When submitting an application, businesses are required to submit proof on the basis of use of the business premises where activities will be carried out. If they own premises – they need to submit an real estate deed or the latest property tax decision, and in case of rented office – a lease agreement certified by a public notary and the real estate deed, or the latest property tax decision.

However, newly established business entities often do not own or rent business premises but, in some cases, use offices within business incubators or other support organizations, or have agreements allowing them to use office space free of charge. This means that such businesses cannot provide the required documents and are unable to use the support program.

PROPOSED SOLUTION

Amend the practice of open calls for programs encouraging entrepreneurship development through financial support for first-time businesses and youth, so as to accept any legal basis for using premises, in addition to proof of ownership or rent – e.g. a statement-approval of the owner for performing business activity in their premises without a fee, a decision on assigning premises for use etc.

This will ensure that the goal and scope of this program is fully achieved, by enabling the majority of newly-established businesses to apply for the business improvement program.

We highlight that the support funds are not allocated for office adaptation, hence the legal basis for the use of premises should not be important. If the goal of this requirement is to prevent misuse, we find that this purpose can be achieved through evaluation of specific cases using other adequate criteria, e.g. who is the founder of the business and what are the related entities to the business and its founder etc.

REGULATIONS: Decree on determining the Program for encouraging entrepreneurship development through financial support for first-time businesses and youth (adopted for the budget year)
Program for encouraging entrepreneurship development through financial support for first-time businesses and youth

3.11. ENABLE AND GOVERN THE CONDITIONS FOR INVESTMENTS OF VOLUNTARY PENSION FUNDS IN AIF VENTURE CAPITAL

Ministry of Finance, National Bank of Serbia

PROBLEM DESCRIPTION

Venture capital investments in the Republic of Serbia are at a considerably low level. During 2022, there have been only three newly registered alternative investments fund management companies (AIFMC) and alternative investment funds (AIF) in the public registries of IAFMC and AIF managed by the Securities Commission. Low share of venture capital in Serbian economy is also indicated by the World Bank's international venture capital availability index, with Serbia reaching 2 to 2.5 out of a maximum value of 7.

The adoption of the Law on Alternative Investment Funds has established the regulatory and institutional grounds for the functioning of VC funds (AIF venture capital), but there is a need to align other regulations, as well as the administrative and business practice, so as to create the conditions for a greater scope of VC investments by these funds, and ultimately, encourage the development of micro, small and middle-sized innovative businesses they invest in. Article 191 of this Law prescribes that a venture capital AIF is - an AIF with private offer whose assets, in line with AIF rules of business, are predominantly invested in newly-established or early-stage businesses, that show business growth and expansion potential as estimated by AIFMC. AIF venture capital investments in such businesses must be in the form of equity instruments or quasi-equity instruments.

The current Law on Voluntary Pension Funds and Pension Plans, in its Article 31 and the Decision on detailed conditions and maximum investment amounts of voluntary pension fund assets, as well as the conditions and manner of investing these assets abroad, do not prescribe that the voluntary pension funds assets can be invested in AIF venture capital. Additionally, Article 31 of this Law also limits the investments into shares of listed companies only to foreign business entities, meaning that domestic businesses are excluded even if they are listed on foreign stock exchange markets.

A best practice example is the Law on Insurance, whose Article 131, Paragraph 2, Item 8 prescribes that technical reserve funds of insurance companies can be used to obtain ownership shares in businesses headquartered in Serbia, which opens the possibility of investing these funds into AIF venture capital shares.

PROPOSED SOLUTION

We propose the following amendments to Article 31 of the Law on Voluntary Pension Funds and Pension Plans:

- amending Item 7) by deleting the word „foreign";
- adding new Item 12) to read: „12) shares of venture capital alternative investment funds".

Innovation activities have high profit potential and encouraging their development stands as a common interest. Therefore, the Law on Voluntary Pension Funds and Pension Plans should enable that voluntary pension funds assets can be invested in venture capital AIF shares, in the same manner as is allowed for insurance companies, that are also regulated financial sector subjects under supervision of the National Bank of Serbia and professional investors, whereby we find it legally safer to, unlike the Law on Insurance, explicitly prescribe venture capital AIFs as investment subjects. At the same time, it is possible to limit the amount of pension fund investments into venture capital AIF shares. This can be done by setting a percentage limit („threshold") in the amount of voluntary pension fund assets, and a percentage limit of the share in equity capital of VC AIF, and by combining these two limits. It is possible to start by allowing minimum amounts in accordance with EU regulations, and gradually increasing the „thresholds" up to a maximum determined by the EU, as the professional investor gains knowledge and experience in the field of venture capital and reaches a position to evaluate the results of their investments into venture capital.

REGULATIONS: Law on voluntary pension funds and pension plans (Official Gazette of RS, No. 85/2005, 31/2011)

3.14. SPECIFY THE CONDITIONS FOR DOCUMENTING THE COSTS ARISING IN THE CREATION OF DIGITAL ASSETS

Ministry of Finance

PROBLEM DESCRIPTION

The problem that occurs with the taxation over digital assets disposal is related to determining the purchase price as actually paid price. This refers to the amount of expenses incurred by a taxpayer when acquiring digital property.

Article 74 Paragraph 10 of the Law on Personal Income Tax prescribes that, in case of transfer of digital assets, the purchase price shall be deemed the price documented by the taxpayer as the actual paid price, while in the case of transfer of digital assets acquired by providing the service of computer verification of transactions in information systems referring to certain digital assets (so-called digital asset mining), the purchase price shall be deemed the amount of expenses a taxpayer had related to acquiring digital assets, that can be documented.

Exceptions to this rule occur in case of mining digital assets that were subject to taxation in line with Article 85 Paragraph 1, Item 16 of the Law (all other revenues not taxed on different basis or not exempt from taxation or from paying taxes under this Law); and in case of transfer of digital assets acquired by the taxpayer from an employer or an employer-related entity free of charge or under preferential price.

However, neither the Law, nor the Rulebook on the tax forms for determining the personal income tax payable by a tax decision, do not prescribe what shall be considered the proof for determining the purchase price. Therefore, the accounting rules apply defining what is considered a reliable accounting document, in line with the Law on Accounting. However, this leaves a legal gap that creates legal uncertainty for taxpayers, bearing in mind the principle of certainty in tax law, i.e. in legal tax relations.

PROPOSED SOLUTION

The first step in resolving this problem is the preparation of a study on the functioning of digital assets trade, which would serve as a basis for determining which documents shall be considered evidence for determining the expenses arising in the creation of digital assets (e.g. electronic confirmation from a digital platform / market exchange on the performed transaction, minus the fee paid to the platform or market, on a predefined form etc). The study would also analyze the issue of providing evidence to gains and losses.

This should be followed by further steps:

- Amendments to the Law on Personal Income Tax should govern the manner of documenting the purchase price of digital assets, or expenses arising from the creation of digital assets;
- Adoption of a specific rulebook should further specify the manner of documenting the purchase price of digital assets.

REGULATIONS: Law on Personal Income Tax (Official Gazette of RS, No. 24/2001, 6/2023)
Specific rulebook that would govern the manner of documenting the purchase price of digital assets

4.5. DEFINE THE CONCEPT OF A SAMPLE OF SIGNIFICANCE FOR RESEARCH AND DEVELOPMENT

Ministry of Finance; Line ministries responsible for special laws

PROBLEM DESCRIPTION

Samples imported for laboratory testing, i.e. for research and development purposes, are subject to regular border controls and customs procedures, which last at least seven days, and often significantly longer. This practice makes it impossible to examine the sample in the intended way, since it changes its properties during the time it is kept at the border, even though these samples are completely consumed and destroyed within the scope of the examination, i.e. research, so they do not come into contact with consumers and protected goods.

The Customs Law prescribes the specific treatment of "authorized business entities" (Art. 27-29), that is, business entities that are seated in the customs territory of the Republic of Serbia and meet a certain set of criteria defined in Article 28 of the Customs Law, namely: the absence of a serious violation of customs and tax regulations, having a high level of control over activities and the flow of goods, financial liquidity, expertise and safety and security standards. These entities are exceptions to the payment of import duties (Articles 246 and 247) since the Customs Law in Article 247, Item 1 prescribes that import duties are not paid on free advertising material and samples received from abroad. That law does not define the concept of a sample that is imported for laboratory testing, that is, for the purposes of research and development, nor does it prescribe a simplified procedure for its import.

Article 42 of the Regulation on Customs Procedures and Customs Formalities prescribes that "authorized economic entity" is subject to fewer physical and documentary controls than other economic entities, i.e. to have a more favorable treatment in terms of risk assessment and control, and Article 182. exceptions in which there is no obligation to submit an entry summary declaration (ENS) when bringing goods into the customs territory. Article 250-256 of the Regulation prescribes the method of checking the goods (inspection, sampling and testing of samples).

Article 23, Paragraph 5, Item 2 of the Regulation on Customs Privileges stipulates that advertising material and samples are considered those samples whose individual value does not exceed 100 EUR in RSD equivalents, and "which are received for the purpose of making an order or offer of goods, for concluding a contract on the production of those goods, as well as for display, testing, etc." In this way, the concept of sample in the customs sense is only partially regulated.

Similarly, there is no simplified procedure or exemption from customs control of samples imported for laboratory testing or R&D prescribed in special laws serving as a basis for carrying out official control/inspection supervision out at the border (e.g. the Law on Food Safety) either.

PROPOSED SOLUTION

We propose to amend the Customs Law by defining the concept of a sample that is imported for laboratory testing, i.e. for research and development purposes. That term can be defined by adding a new Item 24a to Article 4 of the Customs Law, which reads:

"24a) "samples of importance for research and development" - samples that are imported on a non-commercial or commercial basis, for the purpose of research and development, as well as for testing by an authorized laboratory, and which are not intended for sale on the market;"

Additionally, the special laws serving as a basis for carrying out official control/inspection supervision at the border (e.g. the Law on Food Safety) need to recognize this type of samples and prescribe a simplified procedure or exemption from customs control, which is carried out through a single point of contact at customs regarding import of materials for research and development (subject to a special recommendation).

After being regulated in legislation, this matter would be elaborated with instructions, harmonized with the list of goods of importance for research and development.

NEW

REGULATIONS: Customs Law (Official Gazette of the RS, No. 95/2018 138/2022);
Regulation on customs procedures and customs formalities (Official Gazette of RS, No. 39/2019, 144/2022);
Regulation on customs privileges (Official Gazette of RS, No. 38/2019, 86/2019);
Special laws serving as the basis for official control/inspection supervision at the border

4.7. SIMPLIFY THE IMPORT OF UNREGISTERED MEDICAL DEVICES FOR RESEARCH AND DEVELOPMENT PURPOSES

Ministry of Health; Agency for Medicines and Medical Devices of Serbia

PROBLEM DESCRIPTION

At the end of 2018, the Rulebook on the import of unregistered medical devices was amended, in order to enable a simplified procedure at the request of innovative companies and startups, as well as scientific and research organizations, for the import of unregistered medical devices for the purpose of scientific research and development of innovative products. The new Article 9a of the Rulebook stipulates that the request for import for the purposes of research and development of innovative products must be submitted to the Agency for Medicines and Medical Devices (ALiMS). The request shall be accompanied by a certificate obtained from a science and technology park or the Innovation Fund, confirming that the applicant is a member or recipient of funds, or a scientific research organization. ALIMS is meant to approve the import no later than 24 hours after receiving the request. This possibility is prescribed for companies that are members of all science and technology parks (STP) in Serbia and for beneficiaries of innovation incentives. However, in practice, Article 9a of the Rulebook is not applied, because it is not interpreted as an exception to the rule prescribed by Article 2 of the Rulebook, which prescribes that the import of unregistered medical devices can only be carried out through the wholesale of medical devices as an importer (registered in the Registry of issued licenses for the wholesale of medical devices in accordance with the Law on medical devices), and at the proposal of an authorized import proponent (health care institution, private practice, social care institution, humanitarian organization, patient association, ministry responsible for defense affairs and ministry responsible for emergency situations).
In this way, the simplified procedure is practically impossible, which makes innovation activity in the areas related to health and the development of medical devices difficult.

PROPOSED SOLUTION

It is necessary to amend the Rulebook on the import of medical devices, specifically Articles 8, 9 and 9a, so as to give the opportunity to scientific research organizations, innovative entities, and innovation infrastructure entities to directly import, under simplified procedure, the unregistered medical devices for the purposes of scientific or medical research, or for research and development of innovative products.
The amendments should enable them to perform the import directly, as importers, for their own needs, rather than via wholesalers as importers registered in the Register of Wholesalers (Register of licenses issued for the wholesale of medical devices), which is currently the case.
Additionally, we propose that, instead of current procedure of providing evidence about the entity by submitting a statement, the Agency for Medicines and Medical Devices should determine these characteristics ex officio (the status of scientific research organization, innovative entity or innovation infrastructure entity), upon insight into the Register of scientific research organizations or Register of national innovation system entities.
Finally, the import of unregistered medical device requires a statement by an authorized person that such device would be used solely for the purpose of developing innovative products, that it would not be used for clinical trials nor used on patients and for commercial purposes.

PROGRESS ACHIEVED

ALIMS has agreed with the proposal to amend the Rulebook, and the final approval of the Ministry of Health is awaited.

REGULATIONS: Law on Innovation Activities (Official Gazette of RS, No. 129/2021)
Rulebook on the import of unregistered medical devices (Official Gazette of RS, No. 39/2018, 58/2021)

4.8. INTRODUCE A SYSTEM OF COLLECTIVE PERMITS AND NOTIFICATIONS FOR THE IMPORT AND EXPORT OF BIOLOGICAL MATERIAL

Ministry of Health; Agency for Medicines and Medical Devices

PROBLEM DESCRIPTION

Obtaining licenses for the import and export of biological material in practice takes a long time and has an uncertain outcome, which makes it difficult to engage in research and development, as well as to establish new health technologies and treatment of patients in Serbia. This situation is partly a consequence of insufficient capacity of the authority that carries out the procedure for approval of this import-export, as well as the complicated procedure of obtaining a permit.

The permit for the import and export of biological material is issued by the Ministry of Health for individual export/import, for a maximum duration of six months. Permits are therefore issued only for individual cases and for a specific duration. In addition, the persons who act according to the requests often face a dilemma about which code, i.e. tariff label, the biological material belongs to, whereas the permits are issued for that code. The regulatory framework does not follow the development trends in this field, and the practice is uneven and not aligned with the risk associated with a certain biological material.

For example, in the request submitted to the Ministry for the import of blood, there is an obligation to state all data on the blood being imported: purpose, quantity, packaging, frequency of import (e.g. twice for 10 test tubes or a bone marrow sample, 80 ml, in a PVC bag). When this biological material is sent from abroad, the permit is inspected at customs and the shipment is then taken over by the forwarding service. Given that the duration of this permit is a maximum of six months, if during that period there is a need to conduct another type of blood analysis, which is not covered by the issued permit, it is necessary to submit a request for issuing a new permit.

PROPOSED SOLUTION

We propose that the existing system of individual permits for the import and export of biological material be replaced by a system of collective or group permits. In addition, the proposal is to introduce a system of notifications where entities that import or export biological material would inform the competent authority about the intention of each individual import/export and the realization of that import/export.

The implementation of this solution would optimally imply the establishment of a software solution for the Ministry of Health that would combine the following functionalities:

- submitting requests and issuing collective permits to entities engaged in research and development, including health institutions and laboratories, which would be authorized to, within the defined period, i.e. while a certain project/research lasts, import and export biological material for the purpose of laboratory analysis and research and application of new health technologies, without submitting requests and issuing individual permits;
- informing, i.e. sending a notification to the competent authority about the intention of each individual import/export of biological material and the realization of that import/export.

Such software solution would enable linking all institutions that hold public authority in relation with this import-export, as well as other participants in this process (the Directorate for Biomedicine within the Ministry of Health); Agency for Medicines and Medical Devices (ALIMS); Customs Bureau; importer-exporter; forwarder).

In addition to the time limit, the collective permit may contain a limit on the type and quantity of biological materials to be imported/exported, depending on the type of material and research.

Examples of such a solution can be found in the Law on Medicines and Medical Devices and the Rulebook on Clinical Trials of Medicines in Human Medicine, where the service provider for clinical trials can obtain a permit from ALIMS to import a certain substance for the entire duration of the approved clinical study.

NEW

REGULATIONS: Customs Law (Official Gazette of RS, No. 95/2018,138/2022);
Law on Medical Devices (Official Gazette of RS, No. 105/2017);
Regulation on customs procedures and customs formalities (Official Gazette of RS, No. 39/2019,144/2022)

5.1. ABOLISH ARBITRARY RESTRICTIONS AT THE LEVEL OF LOCAL GOVERNMENTS FOR SETTING UP MOBILE RADIO BASE STATIONS

Ministry of Environmental Protection, Ministry of Construction, Transport and Infrastructure, Ministry of Information and Telecommunications

PROBLEM DESCRIPTION

Spatial and urban plans of local governments often include restrictions that determine the minimum distances of radio-base stations for mobile telephony (RBS) in relation to neighboring and certain public facilities objects, which makes the conditions for their placement more stringent than the national law. This practice is not in accordance with the regulations on protection against non-ionizing radiation, the Spatial Plan of the Republic of Serbia, nor with the practice of European Union countries and leads to weaker Internet and mobile telephony coverage in populated areas, where residents, the economy and institutions need it most.

The survey conducted by NALED in March 2021 indicates that planning documents define the conditions for the construction of radio base stations in 38-48% of local governments (10% did not answer). The results indicate that some local governments introduce restrictions through a spatial plan and/or general regulation plan, some through detailed regulation plans, and some through decisions of the Municipal Council or the Municipal Assembly. In this way, various arbitrary restrictions are introduced on the mandatory distance from residential buildings and public facilities (kindergartens, children's playgrounds, schools, religious buildings, hospitals...) which range from 5 to 1,000 meters, and some are prescribed in regarding the height of the antenna pole. This practice of planning at the local level, often accompanied by the inconsistency of planning documents on different hierarchical levels, leads to the factual impossibility of uniform network development and coverage of all necessary zones with a mobile signal and quality improvement of mobile telephony operator services.

Additionally, the Law on Environmental Impact Assessment prescribes that a RBS with effective designated power of 250 W, which is the most common case, may require a study on environmental impact assessment. The decision on whether a study will be required and the details on how the drafting process should look like, is assigned to the local government. In practice, this most commonly means doubling the procedure that is already performed for issuing an expert environmental load assessment, that is submitted by every operator to the line authority based on the Law on Non-Ionizing Radiation. Performing this study significantly complicates and prolongs the entire process, which can also have an uncertain outcome, and it lasts a minimum of 165 days for each base station, not counting the additional time for potential corrections, or a deadline for appeal.

PROPOSED SOLUTION

We suggest that amendments to the Law on Planning and Construction should define the content of planning documents (spatial and urban plans), in order to make it clear how these documents determine the conditions for the construction of radio base stations. In particular, it should be ensured that the planning documents are harmonized with special regulations relevant to the area of RBS installation, and primarily with the Law on Protection from Non-Ionizing Radiation.

We believe that the protection from excessive emission of electromagnetic radiation should be performed in line with the Law on the Protection from Non-Ionizing Radiation, by specifying the mandatory content of the estimation of electromagnetic field scope for each RBS, as well as through mandatory examination of the non-ionizing emission for each active RBS. This way, in most cases, an expert load assessment would be a sufficient document.

We also suggest that the conditions for the construction of RBS be harmonized with EU regulations and practice. It is necessary to transpose the EU directive on measures for reducing the costs of setting up high-speed electronic communication networks into the national legislation. It is particularly important to exclude radio base stations from list 2 of the Regulation and to further specify the content of the Expert Load Assessment, so that the competent authority is guided exclusively by this document, without the need to duplicate the procedure with a request for the preparation of an Environmental Impact Assessment Study.

PARTIALLY RESOLVED

This recommendation is estimated as partially resolved upon the adoption of amendments to the Law on Planning and Construction and the Law on Electronic Communications. On the other hand, the Law on Planning and Construction did not include an amendment that would repeal the existing limitations for RBS. A Bill on environmental impact assessment was passed by the Government, but was not placed into Assembly procedure. Proposals have also been made to the line ministry for amending the Regulation so as to delete the RBS from List 2, and for amending two rulebooks so as to replace the standards that are no longer used. Further on, the EU directive on reducing broadband network costs has not yet been transposed, although new regulation is currently being prepared.

REGULATIONS: Law on Planning and Construction (Official Gazette of RS, no. 72/2009, 62/2023)
Law on protection against non-ionizing radiation (Official Gazette of RS, No. 36/2009)
Law on Environmental Impact Assessment (Official Gazette of RS, No. 135/2004, 36/09)
Regulation on determining the list of projects for which an environmental impact assessment is mandatory and the list of projects for which an environmental impact assessment can be requested (Official Gazette of the RS, No. 114/2008)
Rulebook on conditions that must be met by legal entities that carry out the tasks of systematic examination of the level of non-ionizing radiation, as well as the manner and methods of systematic examination in the environment ("Official Gazette of the RS", 104/2009)
Rulebook on the conditions that must be met by legal entities testing the radiation levels of sources of non-ionizing radiation of special interest for the environment ("Official Gazette of RS", No. 104/2009)

6.1. ENABLE STORAGE OF LOCAL GOVERNMENT DATA IN THE STATE CENTER FOR DATA MANAGEMENT AND STORAGE AND USE OF CLOUD SERVICES

Ministry of Public Administration and Local Government, Ministry of Information and Telecommunications

PROBLEM DESCRIPTION

According to the data NALED's years-long Analysis of Information Systems and Information Security in Serbia, a certain number of local governments show vulnerability of networks and systems. A special problem is the storage of data, which most often includes sensitive data, i.e. personal data of citizens.

The latest analysis from 2020 showed that 62% of local governments believe that their data is at risk, while 74% also estimate that they have fragile parts of the system. Some local governments also use unlicensed antivirus software. Over 80% of local governments store backup copies of data at the location where their primary computer center is located, and 70% stated that they do not have a backup location for data storage. Additionally, over 60% of local governments do not control the outflow of data from local governments. Representatives of local governments recognize the necessity and importance of storing data in a secure manner, but due to the lack of a systemic and long-term solution, various practices are in place that cannot ensure full data security – data is saved, among other ways, via an external hard disk, which is extremely dangerous from a security point of view because there is no adequate data protection system on a medium that is intended for transmission, not for data storage. In a large number of local governments, the devices are located in the same location in the system hall, which represents a major security risk, due to possible electric shock, fire, flood or some other disaster.

The Regulation on the maintenance and improvement of the State Data Management and Storage Center regulates the conditions for the maintenance and improvement of the State Data Center, as well as the method of submitting a request for initiating the procedure of connecting an authority to the resources of the data center, which can be refused by a competent authority.

This Regulation does not regulate the possibility of permanent storage of local governments' data in the data center, so a legal gap has been observed in this part, and there is also no regulation that regulates what data can be stored in the state "cloud" and in what manner.

PROPOSED SOLUTION

In order to solve the problem of keeping the most sensitive data of citizens, managed by local governments, we propose the adoption of a legal framework that would systematically regulate this issue.

We propose the adoption of a regulation that would determine which data managed by local governments is required to be stored in the State Center for Data Storage and Management (Data Center) – telehousing, and the use of cloud services, as well as the conditions and manner this data can be kept in other private or public cloud services. This will enable local governments to store data in a manner that meets all technical and security standards.

Another solution can be seen in building the capacities of the State Center for Data Management and Storage, and establishing regional data centers, serving as branch offices of the State Center for Data Management and Storage, with established Security Operation Centers - SOC, which would improve the availability of resources and ensure the required IT support on the local and regional level.

In this regard, it is necessary to pass a Regulation that would more closely determine the conditions for the use and maintenance of local or regional data centers, based on the Regulation on the maintenance and improvement of the State Center for Data Management and Storage.

NEW

REGULATIONS: The future law that would regulate the obligation to store LGU data in the State Data Center and the cloud and the future Regulation on the maintenance and improvement of local and regional data centers.

Regulation on the maintenance and improvement of the State Center for Data Management and Storage ("Official Gazette of RS", No. 18/2022)

6.2. REGULATE THE CONDITIONS FOR THE IMPLEMENTATION OF TELEMEDICINE

Ministry of Health

PROBLEM DESCRIPTION

Telemedicine is a modern medical method of prevention, diagnosis and treatment of patients using technology by medical and health workers, who are located at a different location than the patient (so-called remote treatment). Although certain regulations recognize this health service, its full potential has not been used, due to inconsistent legal framework and inadequate regulation of the conditions for performing this service.

Rulebook on the content and scope of the right to health care from mandatory health insurance and cost participation for the year 2023 establishes, in Article 28, paragraphs 2 and 3 in connection with paragraph 1, that if the health service - a short visit to the general practitioner , i.e. a specialist is provided to the insured person through available information and communication technologies, the insured person is not obliged to pay cost participation, as well as for the teleconsultation service between the general practitioner with a specialist, or teleconsultation of the insured person with a specialist. These health services are designated by code 333.

Although telemedicine is mentioned in a by-law, its formal legal basis is debatable. The obstacle is provided by Article 160, Paragraph 2 of the Law on Health Care, which prohibits the provision of health services by a healthcare worker outside a healthcare institution, i.e. private practice. Paragraph 3 of this Article defines an exception to this prohibition, stipulating that it is permitted to provide health care by a healthcare worker outside a healthcare institution and private practice, only in the case of performing the activities of an organizational unit, as well as in the case of providing emergency medical assistance.

Also, the Rulebook on detailed conditions for performing healthcare activities in healthcare institutions and other forms of healthcare entities, prescribes detailed conditions in terms of personnel, equipment, space and medicines that must be met by healthcare institutions or other forms of healthcare entities (private practice) in order to establish and perform healthcare activities or tasks, but it does not distinguish between the provision of health services in a conventional way and through information and communication technologies (telemedicine), where a patient receiving healthcare service does not have to be physically present in a health institution or a private practice.

This Rulebook also does not recognize the possibility of establishing an organizational unit or a health institution which exclusively provides telemedicine service (e.g. radiological imaging analysis service), i.e. it does not define closer conditions for performing health activities by a health institution or a private practice that provides telemedicine-remote services, so the general conditions prescribed by the Rulebook on closer conditions for performing healthcare activities in healthcare institutions and other healthcare entities apply accordingly.

PROPOSED SOLUTION

We propose to amend the Rulebook on detailed conditions for performing healthcare activities in healthcare institutions and other forms of healthcare entities, so as to recognize the healthcare institutions and private practice that provide exclusively telemedicine health services, as well as the conditions in terms of staff, equipment and space for establishing such healthcare institutions.

We also propose that the same Rulebook should prescribe detailed conditions in terms of staff, equipment, space and medicines that must be met by an organizational unit of a health institution or a private practice that uses information and communication technologies (telemedicine) to perform healthcare prevention, diagnosis and treatment services, which would take into account the specific way in which this healthcare service is provided.

Also, we propose to amend the Law on Health Care, so as to create a clear and unambiguous formal legal basis for the application of telemedicine.

Application of telemedicine saves time for both doctors and patients, thus increasing doctors' productivity and overall health welfare of patients. Additional important benefits of telemedicine are also higher availability and lower costs. By using telemedicine, a doctor can gain complete insight into the patient's health condition based on the continuously collected data from sensors in real time, instead of physiological measured in the office while patient is at rest, which are sometimes not a realistic picture of what happens in the body during normal daily activities. A patient does not have to come to the doctor's office, but communication can be done via phone or video call, where the doctor transmits observations and findings based on the data, and changes the therapy or gives advice to the patient. Furthermore, telemedicine reduces the possibility of transmission of viral or bacterial infections.

NEW

REGULATIONS: Law on Health Care (Official Gazette of RS, No. 25/2019)
Rulebook on closer conditions for performing healthcare activities in healthcare institutions and other forms of healthcare entities (Official Gazette of the RS, no. 43/2006, 20/2023)

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