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GREY BOOK OF INNOVATION 3.0

Recommendations for improving the conditions for innovative and high-tech entrepreneurship in Serbia 2026 - Summary

FOREWORD

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Dear innovators and friends of innovation,

It is a great pleasure to present the third edition of the Grey Book of Innovation, a publication that contributes to the improvement of the regulatory framework for innovation development in Serbia through dialogue between businesses, science, and institutions. This edition brings a total of 45 recommendations, including 18 new and 37 updated and improved recommendations across eight areas covering various innovation segments. In this third edition, 13 recommendations are marked with the "EU badge", highlighting their particular importance for aligning domestic regulations with the legal framework and practices of the European Union. This way, the Grey Book of Innovation contributes not only to the enhancement of the business environment for innovation but also to the process of Serbia's convergence with European standards.

Through StarTech project, Philip Morris has been supporting the development of innovative entrepreneurship in Serbia for several years. To date, across five cycles of non-refundable grant awarding, 106 innovative projects have been supported with approximately four million euros, alongside additional expert support for teams developing new technologies and entering international markets. Furthermore, through its Innovative Public Policy Lab, StarTech focuses on systemic improvements to the business environment for innovators, encourages dialogue, proposes reforms based on analysis, and provides support to institutions in creating public policies – which is the core of initiatives like the Grey Book of Innovation. In addition to the Grey Book, key initiatives include the Pop-Up Export Hub in Niš, which supports startups in scaling to international markets, and the "Science Caravan", aimed at strengthening cooperation between science and the economy in the fields of technology transfer and industrial doctorates, including the creation of guides and the organization of training sessions. Simultaneously, through communication activities, the project actively promotes innovation, innovators, and Serbia as an attractive investment destination, bringing successful examples of domestic startups and opportunities for investing in innovative projects closer to a wider audience.

We are convinced that this publication's role does not end on paper; rather, it represents a starting point for concrete changes – changes that will stimulate the development of innovation, support the growth of startups and high-tech companies, and, ultimately, contribute to a better quality of life for all citizens.

INTRODUCTION

The Grey Book of Innovation, modelled after NALED's most renowned publication – the Grey Book of Regulations – has, with its two previous two editions, become a recognizable and reliable tool for identifying regulatory barriers and proposing practical solutions in the high-tech entrepreneurship sector. The third edition confirms its status as a benchmark in practice, consolidating inputs from relevant stakeholders and providing guidelines for further development of the innovation ecosystem in Serbia.

The third edition of the Grey Book of Innovation has been developed within StarTech program, entirely funded by a private company – Philip Morris in Serbia, focusing on supporting innovation and the digital transformation of small and medium-sized enterprises (SMEs). The program is aimed at transformation from a traditional into a digital and high-tech economy through direct financial and expert support to businesses, efforts to improve the conditions for innovation, and the promotion of innovators and Serbia as an investment destination. According to the results of the 2025 European Innovation Scoreboard, the Republic of Serbia is categorized as an Emerging Innovator, ranking 31st out of a total of 39 economies. Serbia's performance stands at 51.5% relative to the EU average, leading the Western Balkans region ahead of Montenegro (33rd), North Macedonia (34th), Albania (35th), and Bosnia and Herzegovina (38th). Significant progress has been made in the area of SME innovation, as well as in terms of market penetration and employment in innovative companies. At the same time, there is room for further improvement in the development and export of high-tech products, the strengthening of the intellectual property protection system, increased investment in research and development (R&D), and further enhancement of citizens' digital skills. In order to bridge the identified gap and support Serbia's transition from the group of 'Emerging Innovators' to the 'Moderate Innovators' category, the third edition of the Grey Book of Innovation presents 45 specific recommendations for strengthening the innovation ecosystem and improving the business environment for startups and high-tech companies.

Key ideas for developing the recommendations were gathered through consultations with startups, researchers, and representatives from the academic community and sector associations. The process of collecting these recommendations and the final drafting of the Grey Book of Innovation was coordinated by members of NALED's Innovative Public Policy Lab, with the support of external experts.

Thanks to the development of the innovation ecosystem and the increasing recognition of domestic potential in the fields of technology and entrepreneurship, Serbia has engaged more actively in European innovation initiatives over the recent period. This includes the establishment of the EIT Community Hub in Serbia, which connects domestic stakeholders with the European innovation network. Simultaneously, Serbia's Reform Agenda further strengthens this process by defining innovation as a strategic priority and introducing precise performance parameters and systemic monitoring of results as part of the European integration process.

In this context, the publication places special focus on recommendations for alignment with European Union policies and regulations, which are marked with the 'EU badge'.

The third edition of the Grey Book of Innovation introduces 18 entirely new recommendations. The recommendations that remained unresolved from the previous edition have been re-analyzed and modified where necessary. All recommendations are divided into eight areas:
1. Innovative entities and support organizations
2. Cooperation between science and the businesses

3. Access to finance and payment transactions
4. Taxes and tax incentives
5. Digital assets
6. Import procedures and public procurement
7. Infrastructure and mobility
8. Data usage and healthcare

Similar to the previous edition, this year's Grey Book of Innovation covers a large number of relevant regulations for which amendments are proposed — 36 in total. The highest number of recommendations relates to the Personal Income Tax Law (6), the Law on Innovation Activity, and the Corporate Income Tax Law (4 recommendations each), as well as the Law on Digital Assets (3). Regarding competent institutions, the largest number of recommendations relates to the Ministry of Finance and its directorates —accounting for more than a third of all recommendations. This is followed by the Ministry of Science, Technological Development and Innovation (18%), the Ministry of Health (11%), and the Ministry of Construction, Transport and Infrastructure (9%).

Although all recommendations are important for further stimulating the development of the innovation ecosystem, 10 recommendations particularly stand out, the resolution of which we consider a priority:

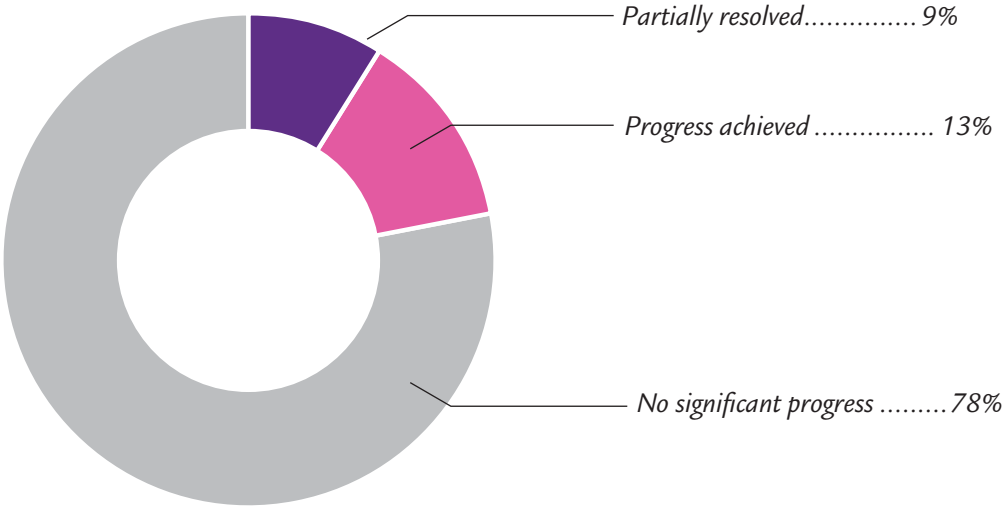
GREY BOOK OF INNOVATION: 10 PRIORITY RECOMMENDATIONS

NO.	RECOMMENDATION TITLE	LINE INSTITUTION
1.3.	Establish a Systemic Framework for the Introduction of a Regulatory Sandbox	Public Policy Secretariat, Ministry of Science, Technological Development and Innovation
1.5.	Introduce Innovation and AI Impact Tests as mandatory elements of the regulatory impact assessment process	Public Policy Secretariat
3.3.	Ensure that eligibility criteria for entrepreneurship support programs do not exclude startups participating in business incubators and other support organizations	Ministry of Economy, Development Fund of the Republic of Serbia
3.8.	Enable online payments in foreign currencies from non-resident consumers	National Bank of Serbia
4.4.	Harmonize the definition of startups across key regulations	Ministry of Finance
5.1.	Enhancing the tax treatment of digital assets	Ministry of Finance
6.3.	Simplify the import of unregistered medical devices for research and development purposes	Ministry of Health, Medicines and Medical Devices Agency of Serbia
6.6.	Improve public procurement of innovations through the application of innovation partnerships and other methods	Ministry of Finance, National Academy for Public Administration in cooperation with the Public Procurement Office
8.2.	Establish a legal basis for sharing public sector data for reuse in research and development of innovations	Ministry of Public Administration and Local Self-Government
8.5.	Introduce a pilot program for a stimulative regulatory regime for clinical trials of medical devices	Ministry of Health

In the coming period, NALED will work dedicatedly on advocacy for the adoption of the recommendations from this edition, with continuous support to competent institutions in their implementation and impact monitoring. We thank all the partners who, through their experience and suggestions, contributed to identifying challenges and defining specific solutions. We promise that – as before – we will work on implementing the proposed improvements from the Grey Book of Innovation from the very first day of its publication.

OVERVIEW OF IMPLEMENTED RECOMMENDATIONS FROM THE SECOND EDITION

Out of the 45 recommendations from the second edition of the Grey Book of Innovation, four have been partially resolved, while progress in the implementation process has been noted for another six. Additionally, one recommendation from the first edition of the Grey Book of Innovation - which fell under the jurisdiction of the then Ministry of Education, Science, and Technological Development and refers to the establishment of a legal framework for the European Research Infrastructure Consortium (ERIC) in Serbia - has been partially resolved. Through amendments to the Law on Science and Research, national legislation has been harmonized with Council Regulation (EC) No. 723/2009, thereby creating the conditions for the establishment of and accession to ERIC consortia.



The highest number of recommendations that have been partially resolved or where progress in the implementation process has been recognized fall under the jurisdiction of the Ministry of Science, Technological Development, and Innovation (four in total), which is consistent with the thematic focus of this publication. In addition to the transposition of the ERIC Regulation, the Guidelines for the Implementation of Cooperation between Science and Businesses within Doctoral Studies – Industrial Doctorates were published in May 2025, aiming to strengthen and systematize this model of collaboration between the academic and business communities in Serbia. The Ministry has upgraded the Open Research Infrastructure platform (e4i), specifically developing the S2B segment dedicated to science-business cooperation, while simultaneously updating the B2B portal for connecting large corporations and small enterprises. These portals are expected to become fully operational in the coming period. Finally, through training programs of the National Academy of Public Administration, more than 8,000 public servants participated in one of 140 training courses in the field of innovation, including digital literacy and the public procurement of innovations.

MINISTRY OF SCIENCE, TECHNOLOGICAL DEVELOPMENT AND INNOVATION	
Strengthening public administration capacities to support innovative entities	Partially resolved
Transposing the Regulation on the European Research Infrastructure Consortium (ERIC)	Partially resolved
Establishing a collaboration platform for all stakeholders in the innovation ecosystem	Progress achieved
Creating conditions for science-industry cooperation through funded doctoral studies	Progress achieved

This is followed by the Ministry of Construction, Transport, and Infrastructure, with two partially resolved recommendations and one where progress in the implementation process has been recognized. Through amendments to the Law on Planning and Construction and the Law on Electronic Communications, the adoption of the Rulebook on Exposure Limits and Sources of Non-Ionizing Radiation, as well as the issuance of instructions to harmonize practices in environmental impact assessment procedures, the conditions for the installation and operation of radio base stations have been improved. These changes pertain to three recommendations from the previous edition of the Grey Book of Innovation.

MINISTRY OF CONSTRUCTION, TRANSPORT AND INFRASTRUCTURE	
Abolishing arbitrary restrictions at the local government level for the installation of mobile radio base stations	Partially resolved
Specifying the conditions for the commissioning and operation of radio base station networks emitting non-ionizing radiation in accordance with EU standards	Partially resolved
Harmonizing prescribed non-ionizing radiation exposure limits with EU standards and improving public information through portals	Progress achieved

Progress in the implementation process has been recognized for two recommendations under the jurisdiction of the Ministry of Finance. In cooperation with the National Bank of Serbia, the Ministry has initiated the drafting of the Law on Crowdfunding, representing a significant step towards aligning Serbia's financial regulatory framework with European Union law and opening possibilities for the future integration of domestic platforms into the single European capital market. Furthermore, amendments to the Regulation on Customs Procedures and Customs Formalities have accelerated the flow of postal and express shipments, which may indirectly contribute to the faster import of samples relevant for research and development (R&D).

MINISTRY OF FINANCE	
Regulating crowdfunding through a legal framework	Progress achieved
Defining the concept of samples relevant for research and development (R&D)	Progress achieved

The Ministry of Internal and Foreign Trade and the Ministry of Health follow, with one recommendation each. By adopting the new Law on the Import and Export of Dual-Use Goods (Official Gazette of the RS, No. 19/2025), the Ministry of Internal and Foreign Trade has partially implemented a recommendation from the second edition of the Grey Book of Innovation. This law has simplified the import procedure for dual-use goods used for research and development (R&D) purposes and introduced the National Control List of Dual-Use Goods. Consequently, organizations utilizing such goods for R&D are now able to import them via a simplified procedure, which is also applied to the import of fair, museum, and exhibition exhibits intended for participation in international events.

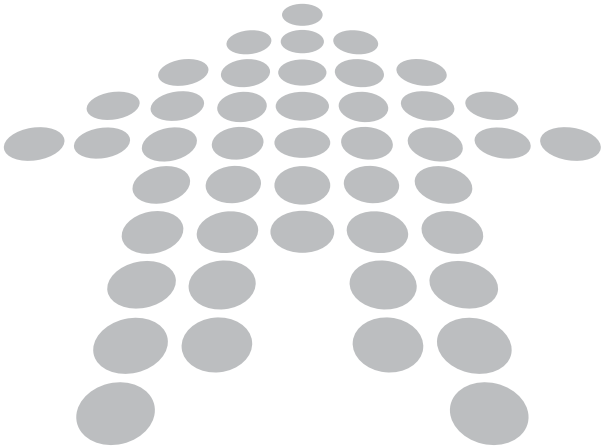
MINISTRY OF INTERNAL AND FOREIGN TRADE	
Automating the procedure for issuing import and export licenses for dual-use goods, particularly those relevant for research and development, to ensure compliance with the 40-day deadline	Partially resolved

The Ministry of Health has initiated work on amending regulations aimed at simplifying cross-border procedures regarding the import of non-registered medical devices. The draft amendments to the Rulebook have been prepared, and their adoption is expected in the coming period.

MINISTRY OF HEALTH	
Simplifying the import of non-registered medical devices for research and development (R&D) purposes	Progress achieved

The progress achieved indicates that change is possible through institutional support and commitment, while simultaneously highlighting the need for additional efforts to establish a stable and encouraging business environment for innovation development. In this context, the Grey Book of Innovation serves as a platform for continuous dialogue between the private sector and the state, aimed at further advancing the reform processes in this field.

10 PRIORITY RECOMMENDATIONS



1.3. ESTABLISH A SYSTEMIC FRAMEWORK FOR THE INTRODUCTION OF A REGULATORY SANDBOX

Public Policy Secretariat of the Republic of Serbia, Ministry of Science, Technological Development and Innovation

PROBLEM DESCRIPTION

A regulatory sandbox is a specific regulatory regime that allows innovative entities to develop and test innovative solutions, business models, or services in an isolated, controlled, and secure environment, without the need for full compliance with existing regulations, subject to prior consent and under the supervision of the competent authority (regulator), for a limited period and within a defined geographical scope.

The establishment and implementation of a regulatory sandbox implies the existence of a law or a secondary regulation that determines who, how, and under what conditions can obtain a permit to conduct such a regulatory experiment. The conditions for establishing a regulatory safe testing environment are as follows: the solution is innovative and brings social or economic value; there is no appropriate regulatory framework for that innovative solution; there is a limited risk to the public interest (safety, health, environment, etc.); the participant is obliged to ensure transparency of operations and cooperate with competent authorities.

The regulatory sandbox has so far come to life in the Republic of Serbia on a modest scale, primarily through the activities of the National Bank of Serbia (NBS) in the field of innovative payment services. The Law on Payment Services has established an appropriate legal basis, within the limited network exemption, for business entities to test innovative payment services they are considering introducing within a limited network of sellers of goods and services or for a limited selection of goods and services. Business entities can, under controlled conditions, conduct testing of innovative payment models without the obligation of obtaining a prior license to provide payment services, but subject to obtaining a prior opinion and allowing the NBS insight into the testing.

Due to the benefits it provides for the development of innovation, the regulatory sandbox is gaining increasing importance and an ever-wider scope of application in comparative systems. The establishment of regulatory sandboxes at the EU level has been recognized as one of the priority goals in the preparation process of the European Innovation Act.

PROPOSED SOLUTION

To enable the wider use of the regulatory sandbox across various sectors, it needs to be regulated at a systemic level by amending the Law on the Planning System that should be further detailed in a secondary regulation - a Decree (which would regulate the classification of regulatory experiments by risk, criteria and methods for assessing the merits of requests, and other matters of importance), whereby specific features in certain areas may be regulated by special laws, in accordance with the nature and purpose of the relations they govern.

With these amendments to the Law on the Planning System, it is justified to prescribe the method for establishing a regulatory sandbox, so that the mechanism is legally secure, harmonized, and undisputed, while simultaneously remaining fundamentally open to initiatives for establishing or utilizing this specific regulatory regime.

An interested entity would, on its own initiative, submit a reasoned proposal for using a regulatory sandbox - based either on the general jurisdiction and authority under the Law on the Planning System, or in the form of an application to a published public call - to the ministry or another body whose scope includes the preparation of regulation drafts or proposals, or the adoption and monitoring of the regulation from which a deviation is requested. The request should include: a description of the innovation/technological solution and expected benefits (with an analysis of expected effects as an annex), a technical and legal analysis explaining why existing regulations represent a barrier, the proposed scope (space/territory, users) and duration of testing, measures for the protection of users and other persons, data protection measures, a proposal for reporting and evaluation of results, a statement of acceptance of conditions and supervision, an ethics committee decision or ethical self-assessment (if applicable), and an exit plan for returning to the standard regime. The act on the introduction of a regulatory sandbox should contain: a permit for limited and controlled testing and application of the new model or solution, a specification of the extent of the deviation from regulations, the obligation for monitoring and reporting, and other relevant elements.

This establishes, in a systemic manner, a legally secure space for testing innovations that, in principle, develop faster than regulations.

The systemic regulation of a regulatory sandbox contributes to alignment with the European approach to regulatory experiments, as recognized within the preparation of the European Innovation Act (emerging regulation), as well as with the practice of implementing regulatory sandboxes in Member States in accordance with the European Commission's (Better Regulation Agenda) principles.

NEW

REGULATION: Law on the Planning System of the Republic of Serbia (Official Gazette of the RS, No. 30/2018))
Decree regulating the classification of regulatory tests by risk, criteria and methods for assessing the merits of requests, and other relevant matters (new regulation to be adopted)

1.5. INTRODUCE THE INNOVATION AND AI IMPACT TEST AS MANDATORY ELEMENTS OF THE REGULATORY IMPACT ASSESSMENT PROCESS

Public Policy Secretariat of the Republic of Serbia

PROBLEM DESCRIPTION

In the current system for drafting laws and other regulations, governed by the Law on the Planning System and its accompanying acts, there is no obligation to assess the impact of regulations on innovation, including the utilization and development of artificial intelligence (AI). Although economic, social, and fiscal effects are analyzed, there is a lack of systematic consideration of the consequences that new regulations may have on innovative entities, AI solutions and their implementation, and the innovation ecosystem in general.

Consequently, regulations are often adopted without recognizing the specific needs of the innovation sector, creating administrative barriers for innovative entities - particularly in research and development, technology transfer, development and utilization of AI tools, and the commercialization of research. An additional challenge is the misalignment of certain regulations with the goals of the digital and green transition, which reduces the predictability of the regulatory environment – an environment that should instead act as a catalyst for these processes.

The lack of an innovation impact assessment also causes our system to lag behind regulatory trends in the EU.

PROPOSED SOLUTION

The proposal is to introduce an Innovation Impact Test as a mandatory component of the regulatory impact assessment process, modeled after the European approach. This instrument would ensure that, from the early stages of drafting laws and other regulations, there is a systematic evaluation of how the proposed legislation affects innovation, startup development, and technological progress, including the utilization and development of artificial intelligence (AI). A specific segment of this test should assess whether a regulation encourages, enables, or restricts the development and use of AI solutions, and whether the potential for implementing AI technologies in the public and private sectors was considered during the drafting process.

To ensure its consistent and uniform application, it is necessary to amend the Decree on Regulatory Impact Assessment, thereby establishing a clear legal basis for introducing the innovation test as a specific component within the analysis of economic effects. This would involve a standardized template and a precisely defined methodology, including the mandatory consideration of the potential for deploying AI tools, automation, and advanced analytics in the implementation of regulations, ensuring that this instrument is applied at all stages of regulatory drafting. In this way, the Innovation Impact Test would complement existing mechanisms, such as the SME Test (Small and Medium-Sized Enterprise Test), allowing for a more comprehensive assessment of the regulation's consequences for the business sector, as well as innovation and technological development.

Alignment with the European approach and the systematic application of this test would contribute to the early identification and removal of regulatory barriers that hinder knowledge transfer, the development of new technologies and innovation – including AI systems – and collaboration between science and industry. Simultaneously, this would enhance the predictability of the regulatory environment and strengthen the innovation ecosystem. The initiative to introduce the European Innovation Stress Test as a regulatory mechanism for assessing the effects of new legislation on innovation capacity and economic competitiveness originated from the European Economic and Social Committee (EESC), which adopted an opinion strongly supporting the integration of this instrument into the European Union's legal framework. According to available information, this proposal is currently in the phase of institutional recommendation and strategic advocacy, with an emphasis on the need to adapt the regulatory framework to the accelerated development of AI and other advanced technologies.

The introduction of the Innovation Impact Test is aligned with the European Economic and Social Committee's initiative on the European Innovation Stress Test, as well as with the regulatory impact assessment approach within the European Commission's Better Regulation Guidelines. This strengthens the Republic of Serbia's readiness for integration into the European innovation and digital regulatory space.

NEW

REGULATION: Decree on Regulatory Impact Assessment (Official Gazette of the RS, No. 20/2025)

3.3. ENSURE THAT ELIGIBILITY CRITERIA FOR ENTREPRENEURSHIP SUPPORT PROGRAMS DO NOT EXCLUDE STARTUPS PARTICIPATING IN 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, implements annual entrepreneurship development programs providing financial support in the form of grants to early-stage entrepreneurs who meet the established criteria. These programs are conducted in accordance with the annual decree defining entrepreneurship incentive programs for startups and youth, as well as the corresponding public call for program implementation.

When submitting an application, businesses are required to submit proof of the legal basis for using the business premises where the activity will be conducted. If the premises are owned by the applicant, a Real Estate Certificate (Title Deed) or the most recent property tax assessment must be provided. If the premises are leased, a lease agreement certified by a Notary Public, along with the Real Estate Certificate or the most recent property tax assessment of the owner, is required.

However, newly established business entities often do not own or lease their own business premises. In some cases, they utilize space within business incubators and other support organizations, while others operate based on free-of-charge space-use agreements. This situation makes it difficult to meet the administrative requirements necessary for accessing specific support programs, thereby limiting access to these measures. Requirements regarding the possession of business premises may have some justification for activities that require physical space, such as 3D printing or prototyping - though even in those cases, their proportionality and purpose can be questioned. For activities that do not depend on physical space, such as IT services, such requirements lack justification and unnecessarily burden these entities' operations and their access to finance.

PROPOSED SOLUTION

Amend the practice within public calls for entrepreneurship development programs providing financial support to startups and youth, so that, when noting business premises where the activity is to be conducted, they accept all legal bases for using the space, rather than only proof of ownership or lease (current practice). These should include, for example, a signed consent form from the property owner for conducting business activities on their premises free of charge, a decision on the allocation of space for use (from incubators or hubs), and other similar documentation.

In this way, the program's objective and scope will be fully realized by enabling the majority of newly established business entities to apply for the business improvement program.

It should be noted that support funds are not allocated for premises renovation, which would otherwise make the legal basis for occupying the space critical. If the purpose of this requirement is to prevent abuse, we believe that such protection can be assessed and achieved on a case-by-case basis through other appropriate criteria - for example, by identifying the company's founder, its beneficial owners, and any related parties.

REGULATION: Decree on Establishing the Entrepreneurship Development Incentive Program through Financial Support for Startups and Youth (adopted for the budget year)
Entrepreneurship Development Incentive Program through Financial Support for Startups and Youth.

3.8. ENABLE ONLINE PAYMENTS IN FOREIGN CURRENCY FROM NON-RESIDENT CONSUMERS

National Bank of Serbia

PROBLEM DESCRIPTION

An increasing number of companies in Serbia, including startups, are selling products and services online to foreign consumers, with online payments processed in accordance with current regulations. However, a significant practical problem occurs: in the final step of the online payment process, non-resident consumers are often presented with an obligation to pay exclusively in RSD (Serbian Dinars). This happens even though the price on the website is displayed in both domestic and foreign currencies and the consumer has chosen to pay in a foreign currency, in accordance with Article 35 of the Law on Trade.

This triggers caution among non-resident consumers, who do not understand why the price at checkout appears in RSD and often conclude that it is a fraudulent transaction. Consequently, a large number of potential consumers abandon their purchases. An additional problem is that the final price charged to the consumer does not match the price displayed on the website due to extra currency conversion costs.

The stated practice stems from a regulatory framework that lacks precision, specifically Articles 32 and 34 of the Law on Foreign Exchange Operations (LFEO). Article 32 of the LFEO stipulates that international payment transactions are conducted in foreign currencies and in RSD, while Article 34 of the LFEO specifies that payments, collections, and transfers between residents and non-residents within the Republic of Serbia must be performed in RSD, with ten defined exceptions where they may be conducted in foreign currencies.

This issue creates legal and operational uncertainty for startups and their foreign consumers, hinders international transactions, and diminishes the competitiveness of domestic innovative companies in the global market.

PROPOSED SOLUTION

We propose that the National Bank of Serbia (NBS) issues an official opinion regarding the application of Articles 32 and 34 of the LFEO in relation to online payments by non-resident consumers. Through this opinion, the NBS should address the following questions:

- Does Article 34 of the LFEO apply to cross-border e-commerce online payments in cases where the payer is a non-resident consumer paying from abroad to a resident merchant in the Republic of Serbia, or does Article 32 of the same Law apply to such situations?
- Is it permitted under the current regime for a non-resident to be charged in a foreign currency during an online purchase from a resident merchant, with the subsequent settlement to the merchant through an authorized bank also performed in a foreign currency, provided that foreign exchange reporting obligations are met?

According to our understanding, the arguments for the application of Article 32 of the LFEO prevail, thereby allowing non-resident consumers – in addition to price display and information – to perform payments in foreign currency. In this regard, we highlight the connection with Article 3 of the LFEO, which stipulates that payments, collections, and transfers for current transactions between residents and non-residents shall be conducted freely. Regarding the "collection" mentioned in Article 34 of the LFEO, as a potential link for its application and the obligation to pay in RSD, we believe that the collection is not performed within the Republic, but abroad. This is in accordance with Point 4 of the Instructions for Implementing the Decision on Terms and Manner of International Payment Transactions, which specifies that the "bank of collection" also includes the bank maintaining the non-resident's account from which the payment is debited.

Should the obligation to perform the subject payments, collections, and transfers in RSD remain, we believe it is necessary to amend and supplement the LFEO to enable these transactions to be conducted in foreign currencies.

NEW

REGULATION: Law on Foreign Exchange Operations (Official Gazette of the Republic of Serbia, No. 62/2006 and 19/2025)

4.4. HARMONIZE THE DEFINITION OF STARTUPS ACROSS KEY REGULATIONS

Ministry of Finance

PROBLEM DESCRIPTION

Fiscal (tax) incentives aimed at developing innovation activities are prescribed by the Corporate Income Tax Law – CITL (Article 50j), the Personal Income Tax Law – PITL (Article 21e), and the Law on Mandatory Social Security Contributions – LMSSC (Article 45d).

The criteria for a newly established company performing innovation activities, which entitle it to a corporate income tax credit, are prescribed in the CITL. Furthermore, the PITL and the LMSSC refer to these same criteria when applying exemptions from withholding tax on salaries and contributions for the founder.

Article 50j, paragraph 10 of the CITL defines a newly established company performing innovation activities as a company incorporated no more than three years prior, which predominantly performs innovation activities as defined by the law governing innovation activities, and meets the prescribed anti-abuse and qualification requirements: annual revenue ≤ 500 million RSD, retains rather than distributes profits, operates within the Republic of Serbia, was not created through a corporate restructuring (status change), and either R&D costs account for 15% of total expenses in each tax period, or 80% of employees are highly qualified, or the company is the owner/user of a registered copyrighted work or patent. Registration in the Register of National Innovation System Entities (hereinafter: "the Register") is not established as a condition for exercising fiscal incentives, which was confirmed by the Ministry of Finance's opinion No. 011-00-977/2021-04, dated September 26, 2022.

On the other hand, the concept of innovation activities, innovative entities, and specifically startups, is systematically regulated by the Law on Innovation Activity (LIA) in Articles 2 and 22. This law also establishes the Register (Article 42), while the requirements and procedures for registration are further detailed in the Rulebook (Articles 6 and 7), which differ from those prescribed in the CITL. Among other things, this Rulebook sets a general requirement for a startup to be no more than 10 years old. As a specific condition, it requires that R&D costs account for at least 10% of total expenses in the previous year, or that the entity holds intellectual property rights or other intellectual assets. The rationale for prescribing a longer period for startup existence reflects the protracted nature of innovation development, particularly in the STEM fields, which significantly exceeds the three-year period stipulated in the CITL.

The autonomous definition of a newly established company performing innovation activities (i.e., a startup) within fiscal legislation - which diverges from the requirements and characteristics prescribed by the LIA as the primary law and its accompanying Rulebook - creates more than just legislative inconsistency. It has the potential to lead to inconsistent interpretations and the uncertain application of fiscal incentives in practice, thereby reducing the predictability of tax and financial planning for newly established innovative companies. Furthermore, one of the primary reasons for establishing the Register is to serve as the central verification point for meeting the criteria to attain startup status. Registration should be the fundamental basis for accessing support programs and utilizing tax incentives, in accordance with Article 42, paragraph 2 of the LIA. However, registration is currently not a prerequisite for their use, which diminishes the significance and utility of the Register itself.

PROPOSED SOLUTION

Within the first set of requirements prescribed in Article 50j, paragraph 10 of the CITL, it is necessary to replace the descriptive qualifiers - "which predominantly performs innovation activities as defined by the law governing innovation activities (activities undertaken to create new products, technologies, processes, and services or significant modifications to existing ones, in line with market needs)" - by linking them directly to the company's registration in the Register of National Innovation System Entities. This achieves alignment, legal certainty, and an effective anti-abuse measure, while fulfilling the purpose of the Register in accordance with Article 42, paragraph 2 of the LIA, thereby enhancing its reliability and value. In this manner, the innovativeness of a company (startup) is proven by its entry into the competent register, following a verification of the prescribed requirements in accordance with the Rulebook.

Within this group of requirements, it is expedient to extend the "age" threshold for an innovative company eligible for investment – currently set at a maximum of three years by Article 50j, paragraph 10 of the CITL - to 10 years from the date of incorporation, in accordance with Article 6, item 2 of the Rulebook.

We believe that the second set of requirements under Article 50j, paragraph 10 of the CITL, which contains anti-abuse and qualification rules, should be retained, with two adjustments to align them with the requirements of the Rulebook:

- In item 5), first indent, the requirement that R&D costs account for 15% of total expenses should be replaced with 10%, in accordance with Article 7, item 1) of the Rulebook. Additionally, this condition should be relaxed to apply only to the "previous tax period" (i.e., the previous year) as per the Rulebook, instead of applying to "each previous tax period;
- The third indent in the same item should be deleted, as Article 7, item 2) of the Rulebook already establishes the holding of comprehensively defined intellectual property rights as a condition for startup registration (whereas the CITL restricts this to only two specific types of such rights).

NEW

REGULATION: Corporate Income Tax Law (Official Gazette of the RS, Nos. 25/2001 ... 94/2024)
Personal Income Tax Law (Official Gazette of the RS, Nos. 24/2001 ... 6/2026)
Law on Mandatory Social Security Contributions (Official Gazette of the RS, Nos. 84/2004 ... 6/2026)

5.1. ENHANCING THE TAX TREATMENT OF DIGITAL ASSETS

Ministry of Finance

PROBLEM DESCRIPTION

According to the Personal Income Tax Law (PITL), every exchange of one type of digital asset for another is treated as a taxable event if a capital gain is realized. This approach creates significant difficulties in tracking and documentation, particularly when a taxpayer executes a high volume of transactions within a short timeframe (dozens or hundreds of taxable events). The high frequency of digital asset trading through such exchanges renders the existing taxation model practically unenforceable and disproportionate. Consequently, it incentivizes non-compliance and tax evasion, thereby fueling the shadow economy. Furthermore, considering the economic reality, an individual lacks the actual economic capacity to pay taxes until the digital asset is exchanged for money. The current taxation of digital asset exchanges can lead to a situation where the taxpayer is effectively forced to sell a portion of their digital assets simply to secure the funds needed for tax payments, even if their investment intent is different (this phenomenon can be characterized as "de facto forced monetization of digital assets).

Article 72a of the PITL provides an exemption from capital gains tax on digital assets if the transferor has continuously held the rights, shares, or securities for at least 10 years. This timeframe is entirely unsuitable for digital assets due to extreme market volatility and the rapid lifecycle of technological innovation.

The Corporate Income Tax Law (CITL) allows for a 100% exemption from capital gains tax for legal entities if the gain is reinvested into the share capital of a resident company or an investment fund, whereas the PITL provides only a 50% exemption for individuals reinvesting for the same purposes.

Furthermore, the tax return form PPDG-3R for determining capital gains tax cannot be submitted electronically via the ePorezi portal. Additionally, due to the lack of instructions or guidelines for tax inspectors, there are significant discrepancies in the interpretation of tax return content and the supporting documentation.

PROPOSED SOLUTION

We propose that the provisions of the Personal Income Tax Law (PITL) stipulate that the exchange of one type of digital asset for another shall not be taxed, and that the tax filing obligation and the capital gains tax liability shall only arise upon the transfer of digital assets for monetary compensation, i.e., when exchanging this type of asset for traditional money (fiat currency), while requiring the taxpayer to maintain records of the digital assets' purchase values. The exchange of digital assets for money is the moment when an individual monetizes the realized economic value and, in accordance with financial and tax regulations, realizes a gain, which only then becomes taxable. Furthermore, this approach would simplify the taxation process for these high-frequency and volatile transactions, making it both enforceable and proportionate, while reducing illegal tax evasion and the shadow economy. However, certain limitations could be established in this regard, specifically concerning the timeframe within which the exchange is conducted (e.g., a maximum of three months, after which it becomes taxable) and the total annual exchange amount (de minimis – e.g., 2,000 euros). In any case, the tax base can be determined cumulatively upon the exchange of digital assets for fiat currency. The tax liability would, in all instances, arise upon the exchange for fiat currency, specifically upon the transfer for monetary compensation.

Due to market volatility (especially in cryptocurrencies), the conditions for equating digital assets with real estate, shares, copyrights, stocks, and other securities do not exist; therefore, the 10-year period for tax exemption on transfers is an excessively long timeframe for this asset class. We propose that the period for qualifying for this tax relief be reduced to a maximum of two years, citing the legal solution in the Republic of Croatia as an example, while in Germany, this period is only 12 months.

Furthermore, it is necessary to equalize the right to a 100% capital gains tax exemption for both individuals and legal entities when the proceeds from the sale are reinvested into the share capital of a resident company or an investment fund.

To facilitate the filing of tax returns for income from digital assets, it is essential to enable the electronic submission of the PPDG-3R form via the ePorezi portal. In order to standardize the practices of tax inspectors in this field, it is necessary to prepare official instructions and conduct targeted training sessions.

REGULATION: The Personal Income Tax Law (Official Gazette of the RS, Nos. 24/2001, 19/2025)
The Rulebook on Tax Return Forms for Determining Personal Income Tax Payable by Assessment (Official Gazette of the RS, Nos. 90/2017, 33/2022), which includes as an integral part Form PPDG-3R – Tax Return for Determining Capital Gains Tax.

6.3. SIMPLIFY THE IMPORT OF UNREGISTERED MEDICAL DEVICES FOR RESEARCH AND DEVELOPMENT (R&D) PURPOSES

Ministry of Health; Medicines and Medical Devices Agency of Serbia (ALIMS)

PROBLEM DESCRIPTION

At the end of 2018, the Rulebook on the Import of Unregistered Medical Devices was amended to enable a simplified procedure for innovative companies, startups, and research organizations to import unregistered medical devices for scientific research and the development of innovative products. The new Article 9a of the Rulebook stipulates that the import request for research and development purposes of innovative products shall be submitted to the Medicines and Medical Devices Agency of Serbia (ALIMS). The request must be accompanied by a certificate issued by a science and technology park and/or the Innovation Fund, confirming that the applicant is a member or a funding recipient, or a certificate verifying that the applicant is a research and development organization. It is stipulated that ALIMS shall approve the import no later than 24 hours upon receipt of the request. This possibility is prescribed for member companies of all science and technology parks (STPs) in Serbia and for beneficiaries of innovation incentive funds.
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. Article 2 stipulates that the import of unregistered medical devices may only be carried out through a medical device wholesaler as the importer (which, in accordance with the Law on Medical Devices, is registered in the Register of Issued Licenses for Wholesale Trade of Medical Devices), upon the recommendation of an authorized import proposer (health care institution, private practice, social welfare institution, humanitarian organization, patient association, the ministry in charge of defense, and the ministry in charge of emergency situations). The application of the simplified procedure in this manner is practically impossible, which hinders innovation in health-related fields and the development of medical devices.

PROPOSED SOLUTION

It is necessary to amend the Rulebook on the Import of Unregistered Medical Devices to allow registered innovative entities - whether legal entities or sole traders - as well as innovation infrastructure entities, to directly submit requests and import unregistered medical devices for research and development purposes in their own name and for their own account via a simplified procedure. This reflects the original intent of Article 9a, ensuring that such imports are not mandatorily conducted through a wholesaler registered in the Wholesale register (Register of Issued Licenses for Wholesale Trade of Medical Devices).
The new provisions of this Rulebook should also prescribe the list of documentation that an applicant for the import of unregistered medical devices must submit to ALIMS along with the import request. We point out that, instead of the current procedure of proving the entity's status by submitting a statement, ALIMS is obliged under Article 103 of the Law on General Administrative Procedure (ZUP) to ex officio verify the status of an innovative entity or an innovation infrastructure entity by accessing the Register of Entities of the National Innovation System, whose data are available online. Furthermore, the amendments to the Rulebook should prescribe the content and electronic form of the approval (the decision on approval) issued by ALIMS, while maintaining the 24-hour deadline for its issuance.

PROGRESS ACHIEVED

The Ministry of Health and ALIMS, in cooperation with NALED, have prepared and harmonized a proposal for the amendments to the Rulebook, the adoption of which is expected.

REGULATION: The Rulebook on the Import of Unregistered Medical Devices (Official Gazette of the RS, Nos. 39/2018, 58/2021)

6.6. IMPROVE PUBLIC PROCUREMENT OF INNOVATIONS THROUGH THE APPLICATION OF THE INNOVATION PARTNERSHIP MECHANISM AND OTHER METHODS

Ministry of Finance, National Academy of Public Administration (NAPA), in cooperation with the Public Procurement Office (PPO)

PROBLEM DESCRIPTION

The definition of innovation within the current legislative framework is inconsistent, which creates legal ambiguity and hinders the practical application of public procurement of innovations.

Specifically, the definition of innovation in Article 2, item 19) of the Public Procurement Law (PPL) differs from the definitions of innovation in Article 2, items 3)–7) of the Law on Innovation Activity (LIA), even though the LIA serves as the framework law in the field of innovation. Instead of clearly referencing the LIA, the PPL complicates the definition by introducing additional social and related elements, which is normatively unnecessary and contributes to ambiguity and inconsistent interpretation.

Additionally, the institutional and procedural framework for the public procurement of innovations is insufficiently developed. Although the Public Procurement Law provides for the possibility of innovation partnerships, this instrument is almost never used in practice, nor is it systematically promoted.

Furthermore, Article 29, paragraph 1 of the Public Procurement Law stipulates that the estimated value of a procurement must be based on conducted market research (including checks on price, quality, warranty periods, maintenance, etc.), while Article 89, paragraph 1 simultaneously states that the contracting authority may conduct market research prior to initiating the procedure. Such a normative solution creates internal inconsistency, as it remains unclear whether market research is an obligation or an option. Additionally, the Law does not regulate the content, scope, or methodology of market research, which is particularly problematic in the procurement of innovative solutions.

Finally, the Public Procurement Portal lacks a specific designation or field to identify that a procurement relates to innovation, which prevents the monitoring, analysis, and evaluation of these procedures at a systemic level.

PROPOSED SOLUTION

In order to improve the implementation of the public procurement of innovations, the following measures should be undertaken:

- Harmonize the definition of innovation in the PPL with the definitions in the LIA. The most legally secure method for harmonization is for the PPL to directly reference the definitions of innovation and its types as specified in the LIA. If, however, the social objective of innovation is retained within the definition in the context of public procurement - given its stipulated in Directive 2014/24/EU on public procurement - it must be clearly defined and elaborated, specifying its purpose and practical application in a manner consistent with the provisions of the LIA as the fundamental law in the field of innovation.
- Develop and systematically encourage and promote innovation partnerships through expert assistance provided by the Public Procurement Office (Article 179, item 6) of the PPL, including the preparation of guidelines, manuals, practical guides, model documentation, and pilot projects, in order to make this instrument accessible and applicable for contracting authorities in practice
- Explicitly establish an obligation in the PPL to conduct market research for the public procurement of innovative solutions, and provide for the adoption of a secondary piece of legislation (a Rulebook) that would further regulate the scope and methodology of market research, as well as the content of the market research report.
- Introduce a specific field or designation on the Public Procurement Portal to clearly identify when a procedure concerns the public procurement of innovations. This would enable the tracking of the number, value, and outcome of such procedures, as well as the evaluation of their effects.
- Implement continuous and targeted training programs for public procurement officers and contracting authorities in the field of innovation procurement, as well as for bidders, focusing on: understanding the legal framework, applying innovation partnerships, managing risks in innovation procurement, and aligning public procurement with public policy objectives.

Improving the public procurement of innovations through the application of innovation partnerships directly contributes to harmonization with Directive 2014/24/EU of the European Parliament and of the Council on public procurement, which introduced this instrument as a mechanism to encourage innovation through public demand..

NEW

REGULATION: Public Procurement Law (Official Gazette of the Republic of Serbia, Nos. 91/2019 and 92/2023)
Bylaws and other acts for the implementation of the Public Procurement Law

8.2. ESTABLISH A LEGAL BASIS FOR SHARING PUBLIC SECTOR DATA FOR REUSE IN RESEARCH AND DEVELOPMENT OF INNOVATIONS

Ministry of Public Administration and Local Self-Government, Ministry of Science, Technological Development and Innovation

PROBLEM DESCRIPTION

Innovative and other companies conducting research and innovation development, along with researchers and startups in the Republic of Serbia, often face limitations in developing advanced digital, predictive, and AI solutions due to a lack of access to relevant datasets held by the public sector. Although certain public sector datasets are publicly available for reuse as open data, many of those critical to the development of innovation remain beyond the reach of innovators. These include energy, transport, health, and social data essential for the development of predictive diagnostics, capacity analysis, resource optimization, smart city development, transport enhancement, energy efficiency, services for vulnerable social groups, and more. For instance, the reuse of health data can support the research and development of innovative solutions for persons with disabilities. Additionally, the existing mechanism for free access to information of public importance is unsuitable for these purposes, as it does not provide the format, continuity, frequency, scope, technical standards, procedural and contractual framework, security mechanisms, and automated channels necessary for the development of innovative solutions. Furthermore, public administration authorities are unable to share pseudonymized data - which, although protected in a prescribed manner regarding the identity of the data subjects, remain personal data under a special regime. According to the Law on Personal Data Protection (LPDP), Article 12, authorities cannot rely on legitimate interest as a legal basis, and the consent of the data subject is often unsuitable as a basis, primarily due to the large number of individuals, administratively complex procedures, uncertain outcomes, and similar factors.

Despite the systemic lack of regulation in this area, certain regulations - both adopted and in preparation - do establish such a basis; however, these are of a narrow, sector-specific scope and are few in number (e.g., geospatial data/INSPIRE, and genetic and biomedical data).

PROPOSED SOLUTION

We propose that the Law on Electronic Government (or the Law on Innovation Activity) stipulate a legal basis for the sharing of public sector data with business entities (G2B) for reuse in research and innovation development. In this regard, it is essential to legally prescribe the basis and method for sharing pseudonymized data - which, while protected in a prescribed manner regarding the identity of data subjects, remain personal data under a special regime – in accordance with the solutions of the EU Data Governance Act and the LPDP (GDPR). Data sharing would be possible under established conditions, subject to the obligation to prove the existence of a specific research and development project with a clearly defined objective, the methodology applied, and personal data protection measures. This would also require a prior ethical assessment and an evaluation of whether there is a risk of selective advantage in terms of state aid regulations. In this context, the status of a registered innovative entity would be considered proof of meeting the requirements regarding the performance of innovation activities, and the existence and objective of research and development.

In this sense, sharing would be possible exclusively for the development of a new or significantly improved product, service, process, or technology (pre-competitive phase). Data may not be used for the direct marketing of products or services, nor for other commercial purposes not directly related to the approved research and development during the duration of the data sharing. Sharing would be conducted free of charge, with established exceptions regarding when and in what amount a fee/tax is charged, based on a Data Sharing Agreement. This agreement shall include clauses on the type and scope of data, the purpose of sharing, the period of use, technical and organizational security measures, liability, and the obligation to destroy or return the data upon the expiration of the term.

The conclusion of the agreement would be preceded by a positive decision from the competent authority, and the application would include a Data Protection Impact Assessment (DPIA) and an ethics committee decision/ethical self-assessment. The shared data would be in pseudonymized or aggregated form, while access to classified data would not be permitted. These conditions and methods of data sharing should be further regulated by a Decree, and it is also practical to prepare a model G2B Data Sharing Agreement.

Stipulating a legal basis for the reuse of public sector data for research and innovation development purposes represents harmonization with Regulation (EU) 2022/868 on European data governance (Data Governance Act) and with Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR), thereby strengthening cooperation and the secure use of data in accordance with EU rules.

NEW

REGULATION: Law on Electronic Government (Official Gazette of the RS, No. 27/2018)
Law on Innovation Activity (Official Gazette of the RS, No. 129/2021)

8.5. INTRODUCE A PILOT PROGRAM FOR A STIMULATIVE REGULATORY REGIME FOR CLINICAL TRIALS OF MEDICAL DEVICES

Ministry of Health

PROBLEM DESCRIPTION

The global clinical trials market for medical devices (MD) has doubled over the past decade and is estimated to grow at an annual rate of approximately 7% through 2030. Currently, 46 MD clinical trials are active in Serbia. Unlike clinical trials for medicinal products, which are predominantly funded by international pharmaceutical companies, about a quarter of MD trials have been initiated by sponsors from Serbia (clinical centers, institutes, or domestic startups), demonstrating the potential for further strengthening domestic research organizations in this domain. According to ALIMS data, only about ten new MD studies are initiated annually. Interviews with sponsors highlight high study approval fees, non-compliance with EU regulations, and lengthy procedures as challenges that limit Serbia's attractiveness as a destination for launching studies.

The fees paid by clinical trial sponsors to the Medicines and Medical Devices Agency of Serbia (ALIMS) and the Ethics Committee of Serbia (ECS) are higher than those in comparable countries in the region. For instance, the fee for a medical device clinical trial at a single center in Serbia is approximately 4,300 euros, whereas in Bulgaria, fees for such research range from 200 to 1,500 euros. Additionally, as Serbia is not an EU member state, the costs of conducting trials (imports, customs duties, additional documentation) are higher, and these expenses do not bypass domestic sponsors, given that research components in Serbia must often be imported.

Furthermore, the Law on Medical Devices defines approval deadlines for MD clinical trials at 85 days in cases where a single request for information (RFI) is issued, which is longer than the 70-day deadline prescribed in the EU. Another issue is the non-compliance of domestic regulations with EU standards, forcing sponsors to prepare specific documentation for the Serbian market - both for the initial approval process and for subsequent reporting during the trial implementation.

These factors diminish Serbia's competitiveness compared to countries offering lower fees, faster procedures, and fiscal incentives, which negatively impacts the number of new sponsors, both domestic and foreign.

PROPOSED SOLUTION

We propose that, based on a comparative analysis of international incentive programs and medical device trials (e.g., the European Medicines Agency's "Innovation Task Force," FDA's "Breakthrough Devices"), a pilot program for an incentive-based regulatory regime be defined and tested. This program should primarily target domestic research organizations and companies developing medical devices, with the aim of increasing the volume of development and the number of MD clinical trials in Serbia. Regulatory incentives would primarily include shortened approval periods and reduced study fees for domestic sponsors, while testing could be conducted with a limited duration of 18 to 24 months. Such incentives could be general, applying to all medical devices (MD) developed by domestic sponsors, or focused on specific medical devices in certain therapeutic areas (e.g., oncology) or fast-growing fields such as the application of artificial intelligence in MD. A clearly defined duration for regulatory incentives would allow regulators to measure the effects – such as the number of new projects, time to first patient recruitment, and the level of investment in domestic development – enabling a data-driven decision on potential permanent regulatory changes. On the other hand, domestic researchers would benefit from a clear timeframe for the testing of these measures. This would provide Serbia with an opportunity to position itself as a more competitive destination for clinical trials and to tap into the growing global potential of this market, while encouraging domestic sponsors to launch trials and strengthen their capacities in this domain.

As a prerequisite for such testing, it is essential to harmonize Serbian regulations with EU standards, primarily regarding the documentation required for study approval (e.g. eliminating the requirement for original manufacturer's Declarations of Conformity for medical devices already on the market used as "auxiliary" devices in the trial), as well as reporting methods (e.g. abolishing quarterly progress reports or modifying the methods for reporting adverse events).

The recommendation could be implemented in phases. Pilot regulatory incentives could be introduced through amendments to the Decision on Fees, the Rulebook on Clinical Trials of Medical Devices, and ALIMS's internal procedures, allowing for subsequent adjustments to the legal framework based on the results of the testing period.

NEW

REGULATION: Law on Medical Devices (Official Gazette of the RS, No. 105/2017)
Rulebook on Clinical Trials of Medical Devices (Official Gazette of the RS, Nos. 91/2018, 40/2019)
Decision on Determining the Amount and Method of Payment of Fees for Services within the Competence of the Medicines and Medical Devices Agency of Serbia (Official Gazette of the RS, No. 98/2023)

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