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SAMOILOV Gleb Mikhailovich

**GOVERNMENT REGULATION OF
TECHNOLOGICAL DEVELOPMENT IN THE
VETERINARY BIOPHARMACEUTICAL SECTOR
IN THE RUSSIAN FEDERATION**

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ANNOTATION

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Academic supervisor:
Oleg Vladimirovich Ivanov,
Doctor of Sciences in Economics, Professor

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Research background and rationale. The current conditions of Russia's economic development and the pursuit of national development goals have increased the importance of sustainable industrial development at the federal and regional levels. Securing technological sovereignty and sustained economic reproduction requires improvements in sectoral and territorial mechanisms. For industrial policy, this entails moving beyond an exclusively macroeconomic focus and giving greater consideration to industry-specific characteristics, the geographical distribution of economic activity and the particular features of innovation cycles. Of particular importance are sectoral mechanisms for sustainable development that combine economic efficiency with the strategic interests of the state.

The development dynamics of the national innovation system are becoming an important factor in long-term economic growth and competitiveness. According to the Institute for Statistical Studies and Economics of Knowledge at the HSE University, despite objective constraints, the manufacture of medicinal products and materials in Russia has shown increasing innovation activity: by the end of 2023 and 2024, almost 30% of organisations were engaged in implementing innovations. Increasing innovation activity in the pharmaceutical and medical industries creates opportunities for related sectors, including the veterinary biopharmaceutical sector. In view of the objectives of technological leadership and food security, the veterinary biopharmaceutical sector acquired a particular place in the country's industrial policy in early 2025. The Strategy for the Development of the Agro-Industrial and Fisheries Complexes of the Russian Federation until 2030 identifies veterinary medicinal products, including vaccines, as one of the country's 'new growth points for the agro-industrial and fisheries complexes'.

The spatial organisation of the veterinary biopharmaceutical sector entails close links with users of veterinary medicinal products, primarily livestock enterprises, calling for a combination of sectoral and regional approaches to industrial policy. The COVID-19 pandemic, which spread worldwide in 2020 and claimed millions of lives, highlighted the interconnectedness of the contemporary global economy and renewed attention to the One Health concept, which recognises the interdependence of human, animal and environmental health. The rapid spread of infection despite the restrictions imposed

demonstrated the intensity of international movements of people, raw materials and finished products, as well as the impossibility of bringing such contacts to a complete halt. The pandemic also confirmed the need for the independent development of science, biotechnology and industry capable of improving preparedness for, and the effectiveness of rapid responses to, new biological risks. Greater public awareness of these interconnections created more favourable conditions for adjustments to government innovation and industrial policy. In Russia, an additional impetus came from the events of 2022, which triggered an acute crisis in foreign economic, technological and scientific relations with many previously key partners.

The contributions of the pharmaceutical industry and the veterinary biopharmaceutical sector to Russia's GDP are relatively small: according to researchers, in 2020 they accounted for 0.4% and no more than 0.1%, respectively. At the same time, many new and emerging human infectious diseases are zoonotic in origin: approximately 60% of all known human infectious diseases and 75% of emerging infectious diseases originate in animals. In intensive livestock and poultry production, expenditure on veterinary medicinal products rarely exceeds 5% of the cost of finished products. Nevertheless, these products are critically important for maintaining livestock populations throughout the productive period and achieving economically significant performance indicators, including weight gain, milk yield, egg production, feed conversion and productivity, which underpin the sustainability of the country's livestock sector.

Despite its relatively late recognition in official statistics—an individual OKVED 2 economic activity classification code was assigned to the manufacture of medicinal products and materials for veterinary use in December 2022—the veterinary biopharmaceutical sector has a long history, considerable scientific potential and an important role in ensuring biological and food security. Since the Soviet period, products manufactured by state-owned enterprises have met 100% of the need for products used to prevent particularly dangerous animal diseases. At the same time, imports account for up to 50% of the Russian market for veterinary medicinal products in certain product categories, while many of the most sought-after products are manufactured by private

innovative companies from countries with the most advanced economic, scientific and technological development. These circumstances make it **important to examine** the specific characteristics of innovation activity and the model of innovation-oriented reproduction in the veterinary biopharmaceutical sector under prevailing conditions.

State of the literature and research gap. Existing research has examined particular technological, organisational and regulatory aspects of the manufacture of veterinary medicinal products and activities across their lifecycle. However, the structure of the veterinary biopharmaceutical sector and the economic characteristics of its actors have received only fragmented attention. Among the most closely related studies is the doctoral dissertation in biological sciences by I. L. Bero, 'Innovative Bioproduction for Improving the Efficiency of Russia's Agro-Industrial Complex', which examines technological, organisational and economic aspects of bioproduction, including veterinary biological products, animal feed and products for crop production. Issues concerning market functioning and the regulation of activities involving veterinary medicinal products have been examined in the dissertations of D. F. Minnebaev (veterinary science) and A. A. Deltsov (pharmaceutical sciences). Notable international contributions include the edited monograph by S. Metwally, G. Viljoen and A. El Idrissi, as well as works by R. P. Hunter, T. R. Shryock, B. R. Cox, R. M. Butler, J. E. Hammelman, M. J. Francis, I. Ahmed and K. Kasraian on the development, manufacture and regulation of veterinary medicinal products. The theoretical foundations of this study also draw on the works of O. V. Ivanov, V. I. Kushlin, A. M. Margolin, A. I. Folomyev and Yu. V. Yakovets on innovation policy, industrial policy and government regulation. Since research has addressed only individual elements of the activities associated with veterinary medicinal products, a comprehensive examination of the economic and institutional characteristics of the veterinary biopharmaceutical sector remains a relevant research task.

The object of research is innovation-oriented reproduction of the veterinary biopharmaceutical sector within the national economy.

The subject of research is the set of economic relationships associated with the transformation of the veterinary biopharmaceutical sector in Russia through

comprehensive innovation-related resource provision across the different stages of its reproduction.

The aim of the study is to develop approaches to improving government regulation of technological development in the veterinary biopharmaceutical sector in Russia, taking account of its resource base and innovation-oriented reproduction. **The hypothesis** is that a combination of instruments of government regulation can be employed to initiate and sustain innovation-oriented reproduction in the veterinary biopharmaceutical sector. The following **research objectives** have been formulated in accordance with this aim.

1. To refine approaches to defining an industry, a sector and a reproduction model as applied to the veterinary biopharmaceutical sector.

2. To provide a classificatory and analytical characterisation of the veterinary biopharmaceutical sector as an object of government industrial policy.

3. To develop a typology and structure of the resource base for sectoral reproduction, taking account of factors, conditions and processes.

4. To develop a mechanism for the sustainable development of the veterinary biopharmaceutical sector.

5. To formulate criteria for the sector's technological development and propose a method for assessing the innovativeness of veterinary medicinal products as the sector's principal goods.

6. To assess the institutional and regulatory conditions of technological development in a comparative international context.

7. To classify and analyse existing and announced government policy measures relevant to the sector.

8. To substantiate levels and priorities of government regulation of the development of the veterinary biopharmaceutical sector, taking account of constraints on its resource base and the stated national development goals.

The study's **theoretical foundations** comprise approaches to structuring the economy and reproduction-based, systems and evolutionary approaches to the analysis of technological development. A central role is played by F. Malerba's concept of sectoral

systems of innovation and production, which examines a sector through the interrelationships among products, knowledge and technologies, actors and institutions. Applied to the veterinary biopharmaceutical sector, this concept makes it possible to consider developers, regulators and other actors involved in activities across the veterinary medicinal product lifecycle alongside manufacturers.

The systems and evolutionary approaches allow the sector to be examined as a dynamic system whose development is determined by interactions among actors, the accumulation of technological capabilities and changes in institutional conditions. Russian theoretical approaches to the analysis of inter-industry complexes and reproduction in the agro-industrial complex are also taken into account. Together, these approaches underpin the analysis of innovation-oriented reproduction in the veterinary biopharmaceutical sector, including the pre-production stage, resource provision and mechanisms of government regulation of technological development.

Research methodology and methods. The methodological framework combines systems, reproduction-based and institutional approaches, making it possible to examine the veterinary biopharmaceutical sector as a set of interconnected actors, stages of reproduction and conditions governing their activities. The study combines sector-wide analysis with an examination of the structure, resource constraints and interactions of individual actors. These approaches are used to characterise innovation-oriented reproduction, develop a typology of the resource base and substantiate mechanisms of government regulation of technological development.

The study employs comparative and structural economic analysis and methods for systematising, classifying and grouping data to analyse the sector's structure; differentiate its actors by stage of reproduction, product range, economic potential and geographical location; and identify regional and interregional clusters. Quantitative and analytical methods are used to develop an approach to assessing the innovativeness of veterinary medicinal products on the basis of the economic significance of the risks they prevent and the relative improvement in the effectiveness of their use compared with existing alternatives. Structural-logical analysis and formalisation are employed to construct an analytical expression for the unit cost structure that accounts for the stages of

reproduction. The research also employs content analysis of strategic, programme and regulatory legal documents to identify government policy objectives and instruments; analysis of institutional changes, including those associated with lists of critical technologies and the adoption of policy-target documents; comparative analysis of Russian and international practices of government regulation; and methods of analogy and abstraction to adapt theoretical approaches from related fields, namely human pharmaceuticals and biotechnology.

The content and scope of the study correspond to the official academic speciality specification for 5.2.3, Regional and Sectoral Economics, particularly area 2.11, ‘Development of mechanisms for the sustainable economic development of industrial sectors, industrial complexes and enterprises’. Within this area, the study focuses on developing theoretical and applied foundations for government regulation of the technological development of an economic sector, namely the veterinary biopharmaceutical sector. The subject matter also intersects with related areas of the speciality specification, including industrial policy (2.10), the assessment of innovation activity (7.9), the formation of markets for industrial products (2.5) and mechanisms for stimulating innovation in the agro-industrial complex (3.7), reflecting the multifaceted nature of the research problem.

Information sources and empirical evidence base: clustering of sources. The study draws on scientific, industry-specific, statistical and regulatory legal materials contained in monographs, books, periodicals, analytical reports, statistical compendia, electronic databases and the media, as well as materials from business conferences, round-table discussions, working meetings and interviews with sector experts. Three clusters of sources are distinguished. The first comprises theoretical studies of innovation, economic structure, industry development and government regulation. The second includes materials on the current state, prospects and regulation of the veterinary biopharmaceutical sector and its associated market. The third covers sources that explain the nature of government objectives and the specific role of the veterinary biopharmaceutical sector and its products in achieving them.

The research is based on the **hypothesis** that, in performing its functions through regulation, coordination, budgeting and resource provision, the state can influence the comprehensive development of the veterinary biopharmaceutical sector, including its technological dynamics, independence and leadership.

Propositions submitted for defence. The following original research findings have been obtained by the author and are submitted for defence.

1. A broader interpretation of the scope and defining characteristics of the veterinary biopharmaceutical sector is proposed, conceptualising it as a complex economic structure encompassing actors involved in the development, manufacture and distribution of veterinary medicinal products. In addition to criteria commonly used in the contemporary literature, particularly similarities in manufacturing operations or products, it is proposed that the sector's specific reproduction structure, high innovation intensity and dependence on government regulation should be considered when designing and determining the range of industrial policy methods and instruments (area 2.11 of the academic speciality specification, 'Development of mechanisms for the sustainable economic development of industrial sectors, industrial complexes and enterprises').

2. A differentiated approach combining industry-based and functional perspectives is used to identify the characteristics and determinants of innovation-oriented reproduction in the veterinary biopharmaceutical sector: the central role of the pre-production stage, characterised by high levels of risk and investment requirements; the involvement of multiple actors in governance alongside the continuing cross-cutting regulatory role of the state; and the integration, inherent in the reproduction process, of resources from different sources and their dependence on scientific and technological progress in other industries. Innovation-oriented reproduction of the veterinary biopharmaceutical sector is defined as the expansion of sectoral supply through innovation, either by introducing new products to the market or by increasing the production efficiency of existing products. These characteristics underpin the proposal to regard the veterinary biopharmaceutical sector as a distinct object of government regulation (area 2.11 and area 2.5 of the academic speciality specification, 'Formation and functioning of markets for industrial products').

3. A conceptual framework for resource provision is substantiated as a system of factor-resources, factor-processes and the conditions governing their use, specific to each stage of reproduction and sufficient to support innovation-oriented reproduction. Using the veterinary biopharmaceutical sector as an example, this framework makes it possible to propose an approach to assessing resource provision for government regulation of technological development (area 2.11).

4. The rationale is established for differentiating sectoral actors and subsequently clustering them according to their involvement in the stages of reproduction, the characteristics of their veterinary medicinal product portfolios, their economic potential and their geographical location. This approach makes it possible to identify nine regional and interregional clusters with a view to subsequently optimising federal budget expenditure on government regulation by combining the resources available through regional budgetary systems with funds from veterinary medicinal product users belonging to the respective clusters (areas 2.11 and 2.5).

5. An original approach to assessing innovativeness in the veterinary biopharmaceutical sector has been developed. For each veterinary medicinal product, it involves calculating the economic significance of the risk prevented by that product and the relative improvement in the effectiveness of its use compared with existing alternatives. Incorporating this approach into decision-making is intended to improve the effectiveness of prioritising government incentives and support measures (area 2.11).

6. For the purpose of industrial policy planning in relation to the veterinary biopharmaceutical sector, two levels of government regulation are proposed: a basic level covering the provision of food security and epizootic security, and an expanded level involving the development of technological and export potential. In the context of the sector's technological development objectives, this differentiation is intended, in view of resource provision constraints and the need to prioritise government support objectives, to maintain a balance between biological and food security and the achievement of national technological sovereignty (area 2.11).

The theoretical contribution of the study lies in substantiating the selection of approaches to the analysis and government regulation of the veterinary biopharmaceutical

sector as a distinct form of economic organisation within the national economy. The study provides the first substantiation of the veterinary biopharmaceutical sector as a distinct sector with an innovation-oriented reproduction cycle in which the pre-production stage plays a central role. An approach to interpreting the sector's technological development as a form of reproduction is proposed; a criterion for assessing product innovativeness is developed; a resource typology is adapted; and an analytical expression for the unit cost structure is formulated. These contributions may be used in further theoretical analysis, the development of relevant indicators and the formulation of sustainable development strategies for sectors characterised by high innovation intensity.

The practical significance of the study lies in the potential application of its findings to support sustained reproduction in livestock production by increasing the availability of effective products for the treatment and prevention of animal diseases. Instruments of government regulation are proposed, including a two-tier structure of objectives, measures to ensure the availability of critical veterinary medicinal products and measures to support innovation potential. Clustering sectoral actors by stage of reproduction, scale of activity and regional affiliation provides a basis for targeted regulation and the optimisation of federal budget expenditure. The findings may be used by public authorities, industry associations, expert organisations and market participants when developing programmes and measures for the sector's long-term development, taking into account food security objectives and the expansion of export potential.

Three works on the research topic have been **published**, with a total length of 4.2 author's sheets, including one article of 1.2 author's sheets in a scientific journal included in the list of publications recommended by the Higher Attestation Commission of Russia, and two articles totalling 3 author's sheets in publications recommended by the Academic Council of RANEPA. The findings have been presented and discussed through the preparation of and participation in relevant events organised by the all-Russian public organisation Business Russia and the Federation Council Committee on Agrarian and Food Policy and Environmental Management, as well as at five academic conferences in 2025: 'Administrative and Legal Regulation and Public Administration in the Economy' (HSE University, Moscow); 'Modelling and Forecasting the Development of Socio-

Economic Sectors' (Kursk State Medical University of the Russian Ministry of Health, Kursk); 'First Bychkov Readings' (National Research Tomsk State University, Tomsk); 'Lomonosov' (Lomonosov Moscow State University–Beijing Institute of Technology Joint University, Shenzhen); and 'Public Administration and Russia's Development: Challenges, Strategies and Prospects' (RANEPA, Moscow). The findings have provided the basis for the concept of a scholarly monograph to be edited by A. N. Panin, Doctor of Veterinary Sciences, Professor and Academician of the Russian Academy of Sciences.

Structure of the dissertation. The dissertation comprises 237 pages, 9 tables, 18 figures and 1 appendix. The bibliography contains 348 references, including 143 research articles and 5 dissertations related to the research topic.

Chapter One, 'The Economic Nature of the Veterinary Biopharmaceutical Sector', examines theoretical and methodological approaches to defining the veterinary biopharmaceutical sector as a complex economic structure and an object of government regulation. It identifies the sector's characteristics arising from the specific nature of its products, high innovation intensity and dependence on government regulation. It substantiates the application of the reproduction-based approach to analysing the sector's technological development, identifies the pre-production stage and determines the role of innovation in expanding sectoral supply.

Chapter Two, 'Assessment of Resource Provision for Innovation Dynamics in the Veterinary Biopharmaceutical Sector', examines the factors and conditions of resource provision for innovation-oriented reproduction in the sector. It proposes a typology of the resource base encompassing factor-resources, factor-processes and the conditions governing their use at different stages of reproduction. It develops a method for assessing the innovativeness of veterinary medicinal products based on the economic significance of the risks prevented and the relative improvement in the effectiveness of their use. It also provides a comparative analysis of international approaches to government regulation of the sector's technological development.

Chapter Three, 'Approaches to Improving Government Regulation of Technological Development in the Veterinary Biopharmaceutical Sector', establishes the place and role of the sector's technological development within the strategic planning

system, including its contribution to achieving national development goals. It analyses the structure of the sector and measures of government regulation. It substantiates the differentiation of sectoral actors and identifies regional and interregional clusters. It proposes a distinction between the basic and expanded levels of government regulation, taking account of constraints on resource provision.

