Секція № 4
ТРАНСФЕР ТЕХНОЛОГІЙ ТА КОМЕРЦІАЛІЗАЦІЯ ІНТЕЛЕКТУАЛЬНОЇ ВЛАСНОСТІ: СУЧАСНІ ВИКЛИКИ ТА МОЖЛИВОСТІ

УДК 614.2:338

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COMMERCIALIZATION OF AN INNOVATIVE AUTOIMMUNE VACCINE IN THE UKRAINIAN MARKET: PROBLEMS AND PROSPECTS

КОМЕРЦІАЛІЗАЦІЯ ІННОВАЦІЙНОЇ АВТОІМУННОЇ ВАКЦИНИ НА РИНКУ УКРАЇНИ: ПРОБЛЕМИ І ПЕРСПЕКТИВИ

КОММЕРЦИАЛИЗАЦИЯ ИННОВАЦИОННОЙ АВТОИММУННОЙ ВАКЦИНЫ НА РЫНКЕ УКРАИНЫ: ПРОБЛЕМЫ И ПЕРСПЕКТИВЫ

Анотація. Розроблена в Інституті експериментальної патології, онкології та радіобіології протипухлинна аутоімунна вакцина, що виготовляється на основі антигенів з пухлинної тканини пацієнта є високоефективною і при застосуванні у комплексній терапії онкологічних хворих значно збільшує виживаність пацієнтів. Вакцина має високий ринковий потенціал як в Україні, так і на міжнародному ринку препаратів з імунотерапії раку. Однак, комерціалізація таких інноваційних розробок часто стикається з рядом перешкод: внутрішніх, з боку установи, та зовнішніх – з боку зовнішнього середовища, у якому функціонує установа. Основною перепоною успішної комерціалізації аутоіммунної вакцини на даний час є саме зовнішній опір – відсутність процедури стандартизації для препаратів, що виготовляються для кожного пацієнта індивідуально. Тому, саме вдосконалення законодавчої бази у даному напрямку, сприятиме прискоренню процесу успішної імплементації аутоімунної вакцини на українському ринку.

Abstract. Developed at the Institute of Experimental Pathology, Oncology and Radiobiology, the antitumor autoimmune vaccine, made on the basis of antigens from the patient's tumor tissue, is highly effective and, when used in complex therapy of cancer patients, significantly increases patient survival. The vaccine has a high market potential both in Ukraine and in the international market of cancer immunotherapy drugs. However, the commercialization of such innovative developments often faces a number of obstacles: internal, on the part of managers and/or managers of the institution, and external on the part of the external environment. The main barrier to the successful commercialization of the autoimmune vaccine at present is the external resistance – the lack of a standardization procedure for drugs manufactured for each patient individually. Therefore, it is the improvement of the legal framework in this direction that will accelerate the process of successful implementation of the autoimmune vaccine on the Ukrainian market.

Аннотация. Разработанная в Институте экспериментальной патологии, онкологии и радиобиологии противоопухолевая аутоиммунная вакцина, изготавливается на основе антигенов с опухолевой ткани пациента является высокоэффективной и при применении в комплексной терапии онкологических больных значительно увеличивает выживаемость пациентов. Вакцина имеет высокий рыночный потенциал как в Украине, так и на международном рынке препаратов с иммунотерапии рака. Однако, коммерциализация таких инновационных разработок часто сталкивается с рядом препятствий: внутренних, со стороны учреждения, и внешних – со стороны внешней среды, в которой функционирует учреждение. Основной преградой успешной коммерциализации аутоиммунной вакцины в настоящее

время является именно внешнее сопротивление – отсутствие процедуры стандартизации для препаратов, изготавливаемых для каждого пациента индивидуально. Поэтому, именно совершенствование законодательной базы в данном направлении, будет способствовать ускорению процесса успешной имплементации аутоиммунной вакцины на украинском рынке.

Innovation in medicine is about the process of turning a product idea into a practical plane, something that can be used, implemented, or it has been achieved and, where possible, should bear fruit in the form of improving the efficiency of the health care system and the prevention of the most common diseases.

Innovations in medicine are new ideas, approaches, drugs, or methods of diagnosis or intervention techniques used in the delivery of medical services (assistance) or in the organization of processes that are perceived as new or that have unique properties. However, when innovating, institutions and individuals face challenges such as resistance to innovation. This resistance is due to the fact that most people by nature are inherent in conservatism and inertia, which significantly complicate the perception of innovation. Also, the healthcare sector in Ukraine has traditions and signs of fairly hypertrophied conservatism.

Internal resistance is the reluctance or complete refusal to participate in the innovation process by the structural and functional units of the institution, managers at different levels, and medical professionals. This kind of resistance to innovation is both conscious and unconscious.

External resistance. Any leading institution is located in other regions, both public and private, which are sold and separated in their activities. Suppliers, employees, visitors, management, public organizations, competitive institutions, and businesses - all of them work in one way or another, using institutions separately. In the period of innovation, such an impact can often go into pressure and resistance because strategic innovations inevitably affect the interests of all entities involved in the institution.

One of the main reasons for the low level of innovative development of medicine is the fragile development of the system of modern organizational and economic instruments of innovative development of health care, intended to fulfill a dual role: first, to stimulate the emergence, design, and implementation of innovative ideas, products, and technologies; second, to shape the market demand for innovation - management, information, and therapeutic diagnostics.

On the other hand, the poor performance of the system management system has been driven by the health and imperfection of diagnostic methods that utilize medical services, which provide irrational structure, and medical care, and may need systems that respond to needs, and apply current standard standards for medical services.

It should be noted that in the process of development or already developed in Ukraine, there are many innovative products in the medical field, especially in the field of oncology. However, most of them cannot overcome the stage from ready-made innovative product to its successful commercialization.

The greatest achievement of modern oncology is the development and implementation in the clinical practice of various biological products that contribute to the creation of anti-cancer immunity. The progress of the world society in this direction is 34% compared to 14% in the main fields of cancer therapy.

Experts believe that auto-vaccines – the most promising direction of the treatment of cancer patients. The United States has made significant strides in this area. However, it was the first time that Ukrainian scientists were able to develop and implement an anti-tumor auto-vaccine that is accessible to all cancer patients.

Scientists at the RE Kavetsky Institute of Experimental Pathology, Oncology, and Radiobiology, National Academy of Sciences of Ukraine have developed a modern treatment for cancer patients - anti-tumor auto-vaccine.

This auto-vaccine is made on the basis of antigens from the tumor tissue of the patient, modified by cytotoxic lectins (CL) - products of synthesis of the saprophytic culture of B subtilis B-7025.

This method of producing vaccines provides them with high specificity and immunogenicity due to the presence of modified tumor-associated antigens and microbial adjuvants.

The use of anti-tumor auto-vaccines in the complex therapy of cancer patients significantly increases their survival time at individual locations and histological forms of malignant tumors, normalizes immunological parameters, and improves the quality of life of patients.

Anti-tumor autoimmune vaccine (AAV) is used in the postoperative period to prevent recurrence and metastasis by increasing the body's anti-tumor resistance, prolonging the life expectancy and improving the quality of life of cancer patients.

Scientists at RE KIEPOR NASU have worked for over thirty years to create the anti-cancer agent.

More than five thousand patients have already tested the vaccine. For the most part, the trials involved people to whom doctors were no longer able to help.

Experts say that the five-year survival rate increases about three times after using an autoimmune vaccine (in the case of breast cancer - about 17%, with gastric cancer more than 30%).

Medication is not universal, and it is made individually for each patient from the removed malignant tumor and blood of the patient. First, doctors receive the full spectrum of the antigens of the patient. These antigens, modify and inject this patient and develop a complete immune response, he responds to their antigens but modified.

Potential consumers of this innovative product can be all public and private medical institutions involved in the treatment of oncology. That is, the market for anti-cancer drugs, even in Ukraine alone, is huge.

Potentially, the commercialization of an autoimmune vaccine is not only a huge step forward in the treatment (or rather, postoperative recovery and relapse prevention) of various cancers but also a very cost-effective, high potential product.

The technology of Ukrainian scientists already wanted to buy foreign companies. But provided the developers renounce their authorship.

The most significant impediment to the successful commercialization of an innovative product is external resistance, and the medication is not allowed in the pharmaceutical market.

The ministry of health requires certification of the vaccine, the developers say. Although the department is well aware that it is not possible to do this, instead of speeding up the process, they do create artificial obstacles. The medication is individual, and the green light will only give him an improved legal framework.

Practically, it is not possible to certify this vaccine, and therefore the use of these antineoplastic vaccines is in the world, but no one questions their standardization. The vaccine is standard for the patient who received this material and for whom it was prepared, not for everyone else.

It is in this direction that the Ministry of Health's assistance is needed to accelerate the process of commercializing an innovative autoimmune vaccine in the Ukrainian market.

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