Medicine and Pharmacy – facts and myths about the development of an innovative pharmaceutical industry in Poland*

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ABSTRACT: *Innovation is fundamental to the pharmaceutical industry and a key to improvements in healthcare. Its effectiveness depends on huge, constant investments in research. This innovative industry directly affects the course of studies in healthcare and medicine. Its efforts translate directly into the length and quality of our lives.*

For several years now, the progress underway in pharmaceutical industry has produced measurable benefits. Doctors have new pharmaceuticals at their disposal, including many types of antibiotics and anti-viral drugs, vaccines and a wide range of drugs which save lives or make them more comfortable. In the near future, ever more efficient cures for neoplastic, rheumatic, neurological, psychic, metabolic, circulatory or respiratory diseases can be expected.

Innovation is necessary. The human population is ageing, and the task of an innovative pharmaceutical industry is to keep it in a good condition.

The use of innovative drugs can translate directly into lowering the costs of illness. A continuous reduction in spending on healthcare has been observed. The costs of inventing an innovative drug are enormous though (US$ 800 million), and studies on a new drug last between 10 and 13 years. An essential element in recovering the incurred costs and ensuring funds needed for new research is protection by patent.

Innovative pharmaceutical companies in Poland are committed to increasing the competitiveness and sustaining the development of not only the market, but also the

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entire pharmaceutical sector. It is a group of companies of crucial importance to the Polish healthcare system, as it influences improvement in the quality of medical services. Through their investments and spending on research and development, innovative companies accelerate economic growth. In Poland, the innovative pharmaceutical industry is represented by the Association of Pharmaceutical Companies Representatives in Poland (SPFFwP).

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The term

In Polish, the word "innovation" means "introducing something new", but also novelty, innovativeness, reform" itself .[1] The word "innovative" is also often used to describe a state or character, for example, innovative economy, endeavours.[2]

Innovation is fundamental to the pharmaceutical industry and a key to improvements in healthcare. Without the innovative pharmaceutical industry, the generic industry would not exist. Constant introduction of innovations determine the functioning of the pharmaceutical market. Peter F. Drucker defines innovation as constant, organized and rational work, a tool which is used to turn a change into an opportunity to take up something new.[3] He stresses that innovation is not an end in itself, but a tool to achieve higher ends, such as the development of societies and humankind. "Systematic innovation consists in purposeful and organized anticipation of changes and systematic analysis of opportunities to innovate which such changes can make possible."[3] Drucker notes that a majority of innovations take advantage of a change that has already taken place, or is underway. Innovations which result in a major change are rare. For the last few years now the progress underway in the pharmaceutical industry, as well as in many other branches of the economy, has brought about measurable benefits. One should not expect, however, that the near future will bring breakthrough discoveries in medicine which will eliminate more diseases.

Drucker also comments on the often disregarded aspect of innovation, namely its cost-effectiveness.[3] The effectiveness of innovation is measured not only by the originality of the innovative solution, but also by its implementation and financial performance. Pharmaceutical innovations bring measurable financial benefits, both on an individual scale – the benefits affect patients directly – and on the scale of the society at large.

Innovation is a costly challenge, however investment is needed so that laboratories can be built and cooperating research teams established. Such endeavours require appropriate protection. The effectiveness of pharmaceutical innovations depends on huge, constant outlays on research. The responsibility for the course of research is borne by the innovative pharmaceutical industry.

Trivialisation of the term

The terms innovation and innovativeness, often reserved for scientific research, have recently become much more widespread, or even trivialized by being overused in other sectors of the economy, for example in advertisements of new products launched on the market. The media advertise a multitude of innovative products: innovative washing powders, washing-up liquids or toothpastes. The word "innovativeness" is often used very narrowly, colloquially – referring, for instance, to a change of packaging, or shifting from tablets to lozenges. An average consumer does not understand the concept itself, and underestimates the role of innovation in pharmacy. This ignorance comes from the fact that besieged with advertisements of so many products people doubt their novelty, not sure whether the fact they are referred to as innovative is not just a marketing trick aimed at increasing sales.

The value of innovation

The long years of toilsome work by thousands of researchers have brought fruit; a variety of antibiotics, anti-viral drugs and vaccines have brought new hope of recovery to patients who have so far been thought of as incurably ill. Innovation drives scientific progress, including the sciences of medicine and pharmacology. In the pharmaceutical society, this term has become synonymous with research and development. "Science is and always has been one of the greatest and most fascinating adventures of mankind. It is a product of creativity which is of crucial importance in Europe in the 21st century", said Philippe Busquin, EU Commissioner for Scientific Research.[4]

Innovation brings savings

Studies carried out by institutions monitoring the use of innovative drugs confirm a number of advantages brought by their launch on the market. The most spectacular examples include the treatment of smallpox, which used to decimate entire societies. New drugs and vaccines have virtually eliminated such diseases as diphtheria, whooping cough, smallpox, river blindness, etc. Polio, which in 1950 killed nearly 2000 American children, has practically disappeared from industrialized countries today thanks to vaccines. Before obligatory vaccination against measles was introduced in the 1960s, more than 3 million children fell ill with the disease each year, and as many as 500 died of it. In 1998 only 100 cases of measles were recorded in the USA.[5]

New drugs have prolonged the lives of millions of people. It has been observed that reduction in mortality rates between 1970 and 1991 was 5 times higher for diseases whose treatment involved the highest percentage of modern drugs. The reduction of mortality by more than 45% was possible thanks to the use of modern drugs. For the 19 diseases with the highest utilization of modern drugs, a reduction of 72.7% in life years lost has been demonstrated, compared to a reduction in life years lost by only 13% among the 19 diseases with the lowest utilization of modern drugs.

In 1900 the average life expectancy was only 47 years; today it is already 76 years. And this is not the scientists' last word, as no one doubts anymore that longer life is largely the result of the victory of pharmacological inventions over diseases.[6]

Another positive sign of the use of new technologies and innovations in practical treatment is a steady decrease of spending on healthcare, including reduced costs of treatment.[7] Thanks to innovative drugs, the productivity of ill people and their caregivers has increased. Absenteeism from work has considerably decreased. Persons suffering, for example, from migraine headaches can now come back to effective work just a few minutes after taking medication. In spite of such unquestionable achievements, the scientists' joy is not complete. Cures for many diseases, such as cancer, stroke, congestive heart failure, circulatory and respiratory diseases and other non-infectious diseases, have yet to be discovered. In recent years, the incidence of these illnesses has increased due to the faster pace of living, environmental pollution and factors related to the progress of civilization.

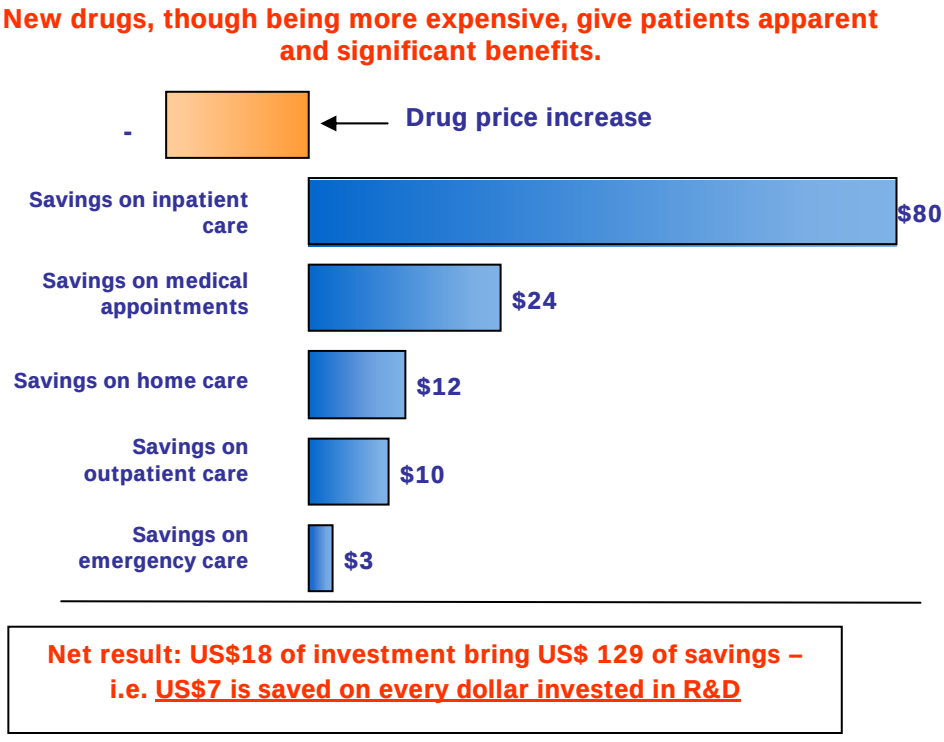
The ageing of populations worldwide will make neoplastic and other non-infectious diseases a large burden on societies. The World Health Organization (WHO) estimates that in 2020 nearly 75%, i.e. about 50 million deaths will be caused by non-infectious diseases, and the load of psychic and neurological diseases will grow faster than the load of circulatory diseases. More and more people are plagued by allergies. The human population is ageing, and the task of the innovative pharmaceutical industry is to keep it in a good condition.

Doctors and their patients have new pharmaceuticals at their disposal, including many types of antibiotics and anti-viral drugs, vaccines and a wide range of drugs which save lives or make patients more comfortable. Innovations in pharmacology keep contributing to improved quality of life. The increased comfort of the lives of many patients is the direct effect of continuous innovative research. The effects of many diseases have been successfully minimized, they are no longer as troublesome for patients as they used to be thanks to the use of modern therapies and solutions.

The constant improvement of insulins and their modernized administration help diabetics to live normal lives. Similarly, persons suffering from asthma have innovative drugs and modern ways of their administration to thank for not having to give up their daily activities. Pharmaceutical innovations also benefit healthy persons who use, for example, modern contraceptives (including the unique transdermal system which is very effective and leaves less room for error).

The future belongs to innovation

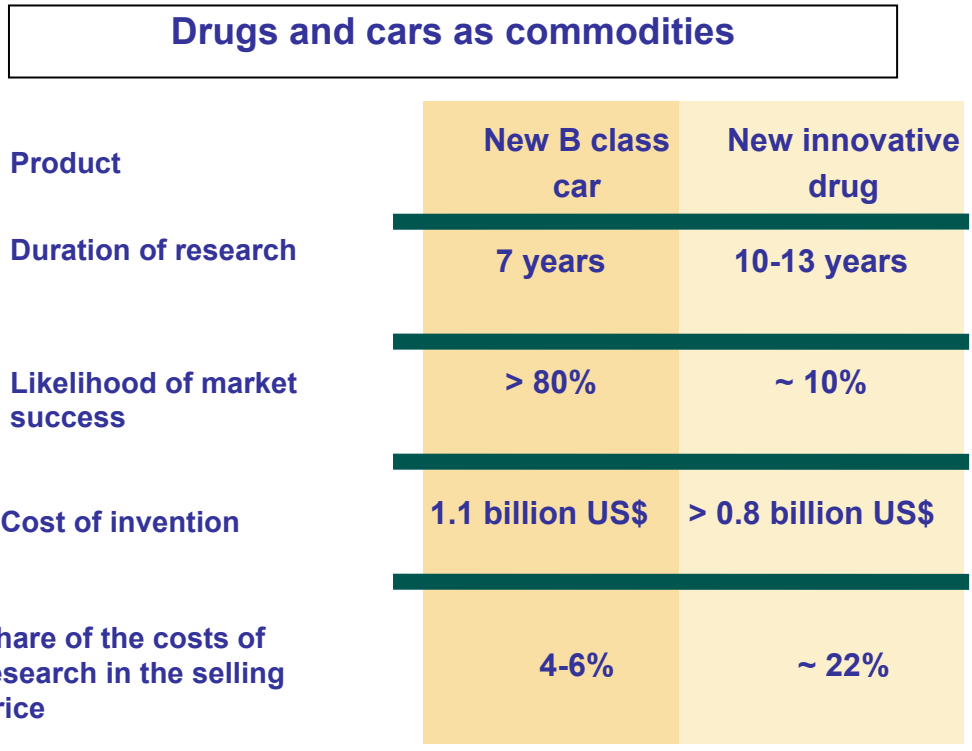
Without introducing innovative products, based on the latest scientific achievements, progress is impossible, both in terms of a single enterprise, and the economy as a whole. The same applies to medicine and pharmacology. Innovative drugs dramatically change the economics of healthcare. The costs of illness are considerably reduced (spending on healthcare, increased productivity of ill persons and their caregivers). The innovative pharmaceutical industry is a key element of the global economy.



Source: Professor Frank Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," NBER Working Paper 8996, June 2002

Costs and risks

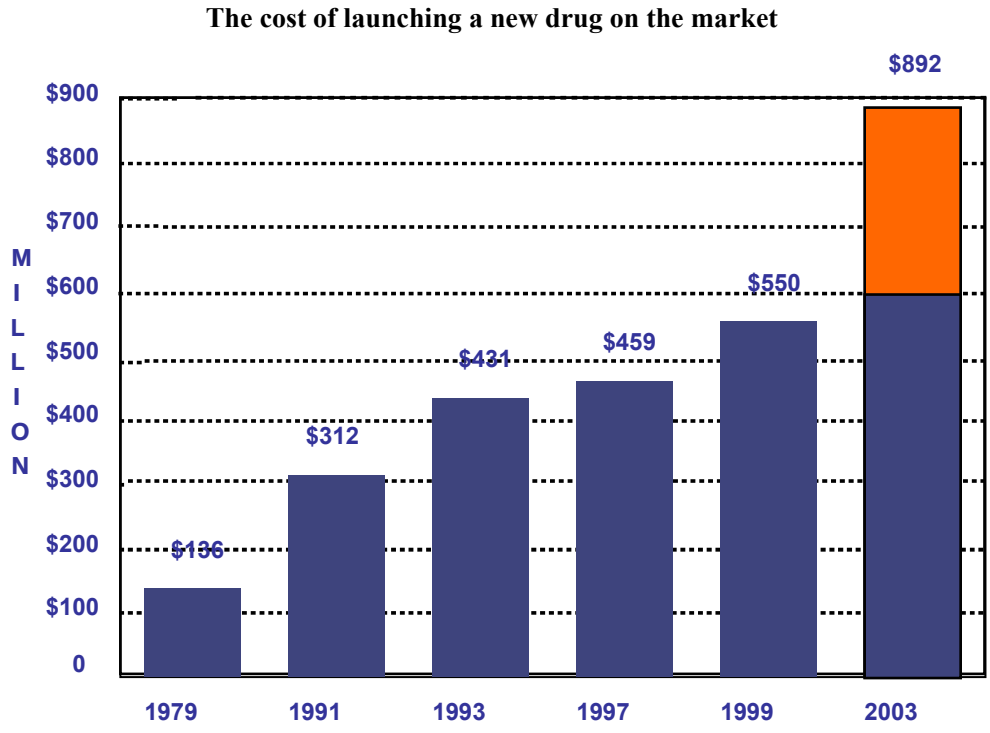
Examples of pharmaceutical innovations can lead to only one conclusion: patients may count on improvement of their condition only with access to modern drugs, and these are produced by the innovative pharmaceutical industry, as it alone guarantees constant search for new therapies and progress in medical sciences. Making this happen is not easy, as innovations are not only very expensive, but are also burdened with a huge risk. This is shown in the following table, which presents a comparison of the costs, risks and time needed to produce a new car and a new drug. The costs of inventing an innovative drug compared to, for example, creating a new make of a B class car are USD 0.8 billion and USD 1.1 billion, respectively. Studies on a new drug last between 10 and 13 years, however, while it takes 7 years to design a new car. The costs of research constitute 4-6% of the car's selling price, compared to about 22% in the case of drugs. And one must remember it is the drug which is a "commodity" whose purchase often determines life or death.



During the industry's many symposia and scientific meetings, pharmaceutical innovation is often referred to as investment in a better quality of life and constant development. These investments are indeed considerable. The pharmaceutical sector is one of those branches of economy whose outlays on research and development are the greatest. The arduous research procedures do not always end in market success. It is estimated that the average cost of launching an innovative drug is about US$ 800 million.

The cost of launching a new drug on the market

The process which begins with research and ends in launching a new drug on the market lasts the average of 11-12 years. Statistically, only a few out of the 5-10 thousand new particles get through the research phase and become components of a marketable drug. It is estimated that 70% of drugs launched on the market cannot generate enough profit to cover the outlays on research and development. Compared to other branches of economy, the risk run by the pharmaceutical industry is thus considerable indeed.[8]



Source: Tufts University for the Study of Drug Development, 2003

Needs determine the value of innovation

The value of pharmaceutical innovation is determined by the needs, first of all by the urgent and constant need for new and innovative drugs and vaccines against the existing, appearing and evolving pathological phenomena.

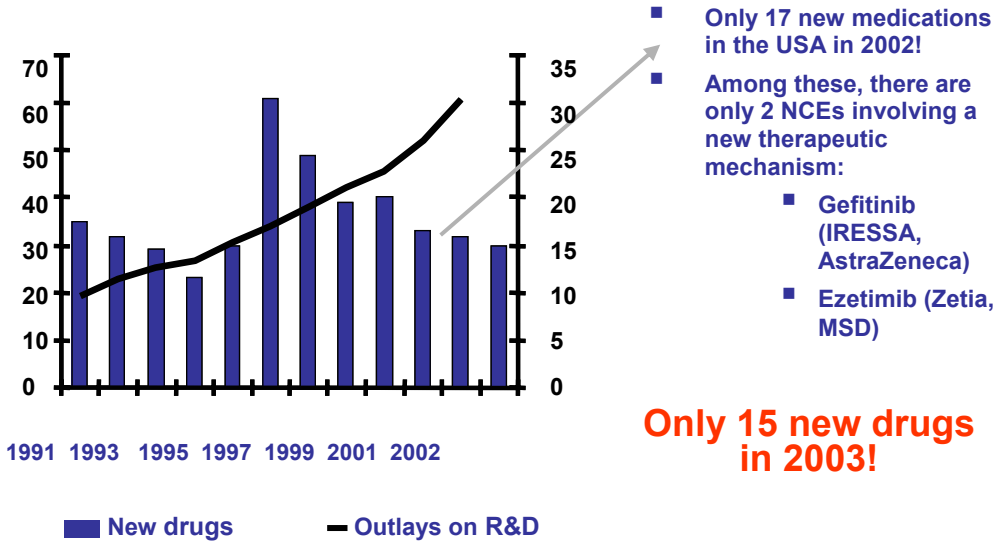
Only pharmaceutical innovations can deal with the increasingly serious problems in contemporary medicine, such as resistance to treatment, mutations, appearance of new viruses, demographic changes which alter disease profiles around the world.

Criticism of innovation

In spite of its achievements, the innovative pharmaceutical industry is often criticized. The media charge it with getting rich at the expense of patients. Some have objections about marketing practices pursued by the pharmaceutical industry. Understanding the principles of marketing and reacting to the needs of clients are basic features of business practice, and innovative industry, like any other, is subject to the rules of the market and provisions of the law, which impose certain behaviours. Complying with both the industry's external and internal norms is a fundamental condition of being able to operate on the pharmaceutical market. It is important, however, that the regulations be transparent, and their interpretation uniform and clear. In Poland, the pharmaceutical

market is regulated by the Pharmaceutical Law Act of September 6, 2001 and its executive regulations. Internal by-laws, which bind, for example, members of the Association of Pharmaceutical Companies Representatives (SPFFwP) in Poland, include, among others, the Pharmaceutical Code of Marketing Ethics for Prescription Drugs. It regulates issues involved in the use of information and the advertising of drugs as part of marketing activities. On the Polish market, these regulations warrant a responsible and ethical attitude of the pharmaceutical industry. This fact is underestimated, however; the innovative industry is talked about without any mention of its achievements and significance for the Polish economy. And they can hardly be disregarded.

The number of new drugs between 1991-2003



Source: CMR International

Innovation in Poland

In Poland, only large companies, those which have consolidated their position on the global pharmaceutical market, can afford to engage in innovative research. These companies are members of the Association of Pharmaceutical Companies Representatives in Poland. Their investments in Poland, the research and development projects they have launched, as well as their production have significantly contributed to the economic growth and increased competitiveness of the entire pharmaceutical branch in Poland.

The innovative pharmaceutical industry has a major influence on shaping the pharmaceutical sector, improving the quality of medical services and stimulating the economic and scientific development.

The Association supports favourable attitudes to the development of innovation in Poland, promotes modern solutions and global achievements in pharmacology which benefit the patients. It brings healthcare benefits to those in need through its continuously pursued charitable projects, and disseminates knowledge of progress in research through its educational meetings.

The significance of innovative companies on the Polish market is clearly demonstrated by the following figures. As of December 2002, investments made by companies which are members of the Association of Pharmaceutical Companies Representatives in Poland exceeded USD 675.6 million and amounted to as much as 78.6% of foreign investments in the domestic pharmaceutical sector.[9] SPFFwP member companies employed 7333 employees, i.e. every third person employed in the domestic pharmaceutical sector. Their spending on research and development and clinical trials in 2002 totalled PLN 162 million (about US$ 40.5 million). Between 1999 and 2002 their combined outlays on this type of projects totalled PLN 471 million. SPFFwP members spent more than PLN 39 million (US$ 9.75 million) on charity (donations and charitable subsidies), and their aggregate spending on charity in the same period totalled PLN 119.5 million (more than US$ 29 million). The combined value of their outlays on educational purposes (including scientific grants) amounted to PLN 17.8 million (US$ 4.2 million); in 2002 alone, pharmaceutical companies associated with SPFFwP spent more than PLN 7 million (US$ 1.7 million) on that purpose.[10]

Polish Problems

In view of what has been said so far, a question appears about whether Poland is a good place for complex innovative projects. Among the advantages it offers is a large market worth US$ 3 billion, and a well trained professional staff. Poland boasts a large number of scientific institutions and schools. The country's potential in that respect is comparable to that of Spain. Disadvantages include lack of dialogue with the authorities, lack of a partner-like relationship. Patent protection in Poland is weak, and the enforcement of legal provisions which are supposed to safeguard its effectiveness is even worse. The authorities turn a blind eye to the registration of generics, in spite of valid patents protecting original products, and puts them on reimbursement lists which the Association has repeatedly pointed out in vain. For nearly 6 years now no new generation drug has been added to the Polish lists of reimbursed drugs. Consequently, patients who want to use innovative drugs must pay more and more for them, even though the level of patient co-payment in Poland is now the highest in Europe. The reimbursement system prefers cheaper generics, and offers no appeal procedures. The strategy of Polish authorities is focused strictly on limiting budget spending at the expense of the patients and their health. This diminishes the standing of companies which invest in development.

A major shortcoming in the development of innovative industry in Poland is the fact that scientific endeavours are pursued in isolation from business activities. The costs of research and development are largely covered by the state budget, which has a number of equally, if not more, urgent expenditures on its agenda. Neither the state nor the industry itself are willing to spend money on research and development, which makes Poland lag far behind other European countries. For example, in the most developed countries, the companies' share in spending on research and development amounts to 65-70%. If the Polish economy is to be referred to as competitive, these proportions must be reversed. In the 15 EU member states, the average spending on R&D, financed from the companies' own resources and the state budget, is four times higher than that in Poland, and exceeds 2.2% of the GDP. In neighbouring countries, for example the Czech Republic, it amounts to 1.35% of the GDP.[11]

The significance and achievements of the foreign innovative industry must be publicized, especially that it is an active contributor to creating a modern healthcare system due to its participation in research projects, and is one of the pillars of the Polish economy. The alarming practices of limiting access to high quality, effective drugs at the expense of the patients' health must not become a rule. If further successes are to be achieved, politicians, medical authorities, charitable organizations, patients and their support groups, as well as the entire medical society need to engage in partnership cooperation.

Assistance from the European Union

The European Union (EU) wants to introduce scientists from its new member states in the main current of research, and integrate innovation within the European Research Area (ERA). This may be possible by strengthening the protection of intellectual property rights and network contacts between the industry and science, as well as increased investments from the private sector. Accession means more changes, as the law which has so far stipulated a 20 year-long patent protection of drugs will now be amended to include an additional provision extending the protection period by the maximum of 5 years. Additionally, the EU applies a 6-year data exclusivity period, during which the manufacturers of generics may not work on the original drugs; there are proposals aimed at extending this period to 10 years. This way the launch of equivalents to the original drugs is further removed in time.

Companies which have joined the Association of Pharmaceutical Companies Representatives in Poland point out benefits following from accession which include an ordering of the market and application of transparent procedures. The registration of drugs will be simplified and shortened, and patients will have better access to the most effective, state-of-the-art therapies.

Poland has huge potential and stands a chance of becoming a European silicon valley of pharmaceutical innovations. Its success depends on the contribution of many sectors: pharmaceutical companies, the Polish authorities, scientists, and intense, systematic work for the development of the pharmaceutical industry in this country.

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