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Innovation
in the Polish health sector:
A quality assessment

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Abstract

This working paper aims at presenting specificity of innovation in the Polish health industry through the prism of experience and opinions of a representative group of fourty-three companies from both the pharmaceutical and med-tech sectors. Analysis of the in-depth interviews strives at better understanding of legal, economic and social mechanisms and phenomena that determine innovation there.

The survey examines first what areas of the Polish health sector are most innovative, what understanding of innovation prevails in the sector, and what is the characteristic of research and development activities carried out there. Subsequent considerations concern an impact of patent law and broadly understood intellectual property on innovation in the Polish health sector. Last, it is surveyed what are other economic and legal instruments stimulating innovation there and how legal regulations and governmental policy could be modified to create an optimal pro-innovative environment.

Keywords: innovation, intellectual property, patents, pharmaceuticals, medical technology

Acknowledgements and Disclaimer

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The views expressed in this article are those of the author and do not necessarily reflect the views of WIPO or its member states.

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INTRODUCTION

chapter 1

1.1 About the project

The project on "IP and Socio-economic Development in the Health Sector in Poland" is a joint initiative of the Patent Office of the Republic of Poland (PPO) and the World Intellectual Property Organization (WIPO) analyzing innovation in the pharmaceutical (pharma) and medical technology (medtech) sectors in Poland. The project focuses on assessing the level of innovativeness within the sectors and the role of intellectual property (IP), particularly patenting. The main research questions intend to shed light on the most innovative specializations, as well as the strengths and weaknesses of the Polish pharma and medtech sectors.

Within the same project, two studies analyze the economic, statistical and patent data of WIPO, the European Patent Office (EPO), the PPO and Central Statistical Office (Wisła and Sierotowicz, 2018; Gołacki et al, 2018). The qualitative part of this project is elaborated in this study.

The aim of this study is to broaden knowledge about the specifics of innovation in the Polish health sector through the prism of the experiences and opinions of a representative group of entities in this sector. Thanks to the research, it is possible to gain a deeper understanding of the legal, economic and social mechanisms and phenomena that determine innovation in this sector. Subjective opinions expressed by representatives of the surveyed entities create a more complete picture of innovation in pharma and medtech, which complements the quantitative results presented in the other two studies.

Firstly, the study determines which areas of the health sector are most innovative, which understanding of innovation – breakthrough or refinement – prevails in the sector, and what are the characteristics of the research and development (R&D) activities carried out. Secondly, the study considers the impact of patent law and broadly understood IP on innovation in the Polish health sector. Finally, it surveys the other economic and legal instruments stimulating innovation in this sector, and examines how legal regulations and governmental policies impact innovation in this sector, taking into account the views of business industry entities on how these could potentially be modified.

1.2 Innovation in pharma and medtech

It is widely accepted that it is necessary to strengthen innovation in the pharma sector. The importance of health sector innovation as a social issue is supported by factors such as aging societies, uncontrolled disease transmissions, and the increasing resistance of viruses and bacteria to existing drugs. In the medtech sector, the perceived importance of innovations is equally significant, as innovations are seen to help prolong and improve the quality of life of patients.

The pharma industry has a highly specific regulatory framework. According to EU pharmaceutical law[1], each medicinal product that is introduced to the market must fulfil safety and efficacy requirements. Original products, comprising new active substances, are authorized based on full data, including results of preclinical tests and clinical trials. The process of development for such medicinal products – from the discovery of a new chemical entity to securing market authorization – is both time-consuming and extraordinarily expensive. Strong legal protection for original medicinal products is seen necessary to compensate for the substantial R&D investment.

Generic products are bioequivalent to the original ones, and so need no preclinical and clinical tests; they can be authorized for the market by reference to the dossier of the original product. The process of authorizing them for the market is much shorter, less complicated and less expensive. This sector of the pharma industry seeks legal instruments which facilitate market accessibility for the follow-on drugs.

On one hand, public health institutions are interested in highly innovative products. On the other, they prioritize access to medicines for patients. Legal regulations concerning protection of innovative medicines need balance the various interests at stake, while keeping pace with rapid technological changes in this sector.

The legal environment for pharma innovations was traditionally associated with patents[2]. However, in recent decades, other protective measures, dedicated specifically to medicinal products, have been introdu-

[1] *Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ EU 2004, L 136/34, with subsequent changes.*

[2] *In the post-TRPIS era, patents are granted in all fields of technology, including for pharmaceutical inventions. See art. 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the General Agreement on Tariffs and Trade of 1994. In Europe, the grant of patents is governed by the Convention on the grant of European Patent of 1973, as amended in 2000.*

ced in the EU law: data exclusivity[3] and supplementary protection certificates[4] both strengthen patent protection for innovative products. The legal instruments supporting the generic sector are Bolar exception[5] and skinny labeling[6].

Since there is no homogeneous reimbursement policy in the European Union (EU),[7] its member states are free to set their own lists of reimbursed drugs, their prices and reimbursement levels, as long as they comply with overall EU regulations, such as the Transparency Directive.[8] Public health institutions of particular countries may benefit from the mechanisms of pharmaceutical pricing and reimbursement which can influence innovative behaviors in pharma markets.

The specificity of the regulatory framework in the pharma sector is clearly related to its division into research-based industry and the generics one.

The medtech industry does not follow this pattern. The regulatory system for medicinal devices – apart from very sensitive innovations, such as transplant technologies – does not have same the high requirements as found in the pharma sector. Companies in medtech are much more diversified in terms of both areas of their economic activities and their levels of innovation. As such, there are no particular patterns that create clear subsectors within medtech.

1.3 Legal environment of the health sector in Poland

Legal regulations in the pharma and medtech sectors in Poland are highly harmonized with EU law. In particular, Polish pharmaceutical law[9] is in accordance with EU Directive 2001/83, constituting Community code relating to medicinal products. The Polish Act on Medical Devices[10] explicitly implements EU Directive 93/42 on medicinal devices.[11]

For the health sector in Poland, IP protection is regulated mostly in the Act of June 30 2000 on Industrial Property.[12] It governs patents and supplementary protection certificates (SPC), as well as protection of trademarks, utility models and designs. It is important to note that the rules of patent protection comply with the rules of the Convention on the Grant of European Patents and with the case law of the EPO. The SPC system complies with Regulation 469/2009.[13] Data exclusivity results from Polish pharmaceutical law, implementing the EU pharmaceutical directive as well as from the regulations on orphan drugs[14] and on pediatric drugs.[15] The Act of 2011 on the reimbursement of medicinal products[16] regulates the principles of financing or co-financing the purchase of certain medicinal products and medical devices for persons subject to general health insurance under the National Health Fund.

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[3] *See art. 10 (1) of the directive 2001/83/EC, ibid.*

[4] *Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009, L 152/1).*

[5] *See art. 10 (6) of the directive 2001/83/EC, ibid.*

[6] *See art. 11 in fine of the directive 2001/83/EC, ibid.*

[7] *Art. 168 (7) of the Treaty on the Functioning of the European Union provides that European Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them (OJ 2012 C 326, consolidated version).*

[8] *Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, pp. 8–11).*

[9] *Act of 6 September 2001 on Pharmaceutical Law (Dz. U. No 126 item 1381 with later changes).*

[10] *Act of 20 May 2010 on Medical Devices (Dz. U. 2015 item 876 with later changes).*

[11] *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169).*

[12] *Act of June 30 2000 on Industrial Property (Dz. U. 2001 No 49 item 508).*

[13] *Footnote 6, supra.*

[14] *Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ 2000 L 018).*

[15] *Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, (OJ L 378/1).*

[16] *Act of 12 May 2011 on reimbursement of medicines, foodstuffs intended for particular nutritional and medical devices (Dz. U. No. 122, item 696 with later changes).*

Innovation usually comes about through the interaction of many actors, including government, industry, universities and research institutions. It also requires an enabling legal environment. Legal mechanisms commonly believed to stimulate innovation in general include patents and broader IP rights. In the context of pharma innovation, this aim is served specifically by supplementary protection certificates and the exclusivity of regulatory data. Beyond that, there are specific legal instruments, such as tax relief, public aid and other financial measures, that may support innovation.

Tax reliefs are granted to taxpayers conducting R&D activities under the Act of 1992 on income tax from legal persons.[17] The taxpayers are entitled to relief in the form of deductions from the tax-based part of the tax deductible costs incurred for this type of activity, i.e. "eligible costs". The amount to be deducted may not exceed 100% or 150% of eligible costs.

Polish entrepreneurs, especially small and medium-sized enterprises (SMEs), may also benefit from various EU financial support programs devoted specifically to innovation activities, in a 2014 – 2020 perspective. These include the Smart Growth Programme, the Operational Programme Eastern Poland, as well as 16 regional operational programs.[18]

The National Centre of Research and Development proposes other programs aimed at pharma companies, such as the general strategic program "Strategmed" or more specific "InnoNeuroPharm".[19]

In the Strategy for Responsible Development, published in 2017 by the Ministry of Development, the biotechnology, pharma and health services sector were indicated as key industries in need of particular attention and as important export and image assets.

1.4 Methodology of the qualitative analysis

The qualitative analysis relies on 42 in-depth structured interviews with Polish health sector companies. The interviews were performed during 2017 and resulted in more than 600 pages of transcripts. The interviews were conducted using the structured interview script detailed in Annex 2.

The analysis was carried out in five sections, each of them applied first to the entities of the pharma sector, and then to the medtech sector. The analysis started with gathering facts and opinions, and then proceeded to group and classify them in order to identify similarities and differences between the sectors. Finally, it concluded with presenting summarized facts and opinions, indicating their approximate degree of representativeness for the whole group – all entities, the vast majority, majority, minority, and none of the entities – as well defining answers to the research issues.

Each part of the analysis, as well as the whole paper, ends with conclusions in which the collected facts and opinions are interpreted in the light of the author's expert knowledge. The views of the author are presented only in the conclusions, whereas the main parts of the analysis present only the views of the respondents.

The main goal of the survey was to gather qualitative information that is not available in traditional statistical sources or IP unit record data. The focus of the questions was on how and why certain innovations are developed and IP decisions are taken by respondents. The sampling process aimed to reflect the characteristics of the entire population as much as possible.

The population of health-related companies – according to the Polish Classification of Economic Activity, PKD, 21.10, 21.20, 26.60 and 32.50 – is approximately 9,500 entities. Some 519 entities from other PKD (the Polish Classification of Activities) sectors which filed patent applications for pharma or medtech were also added to the population. Health-related micro-enterprises – i.e. those with fewer than 10 employees – largely outnumber the small, me-

[17] *Act of 15 February 1992 on the income tax from legal persons (OJ of 2016, 1888)*

[18] *https://www.funduszeeuropejskie.gov.pl*

[19] *http://www.ncbr.gov.pl*

dium and large firms (Figure 1). In the sampling process, the number of micro-enterprises was limited. As a result, there is proportionally two times fewer micro-enterprises found in the final surveyed sample (Figure 2). Accounting for 45 percent, micro-entities still represent the larger surveyed segment. The remaining 55 percent of interviewees are distributed between small (19 percent), medium (14 percent), large (14 percent) and very large (21.5 percent) entities.

Figure 1. Population broken down by the number of employees.

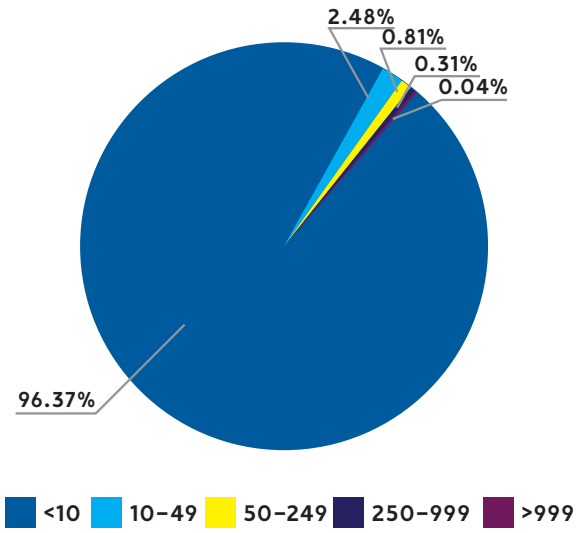


Figure 2. Respondents broken down by the number of employees.

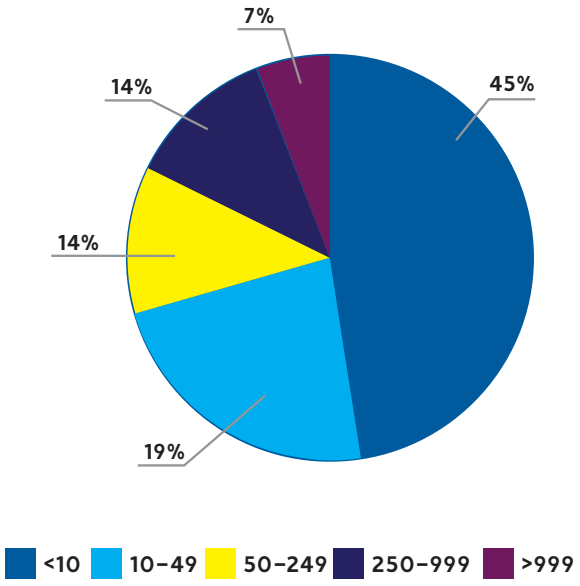


Table 1. Number of patent and utility model applications from respondents.

	Total number of patents and utility model applications	Number of patent applications in the fields of pharma and medtech	Number of utility model applications in the fields of pharma and medtech
Respondents in medtech	**179**	**75**	**27**
Respondents in pharma	**130**	**77**	**0**
Total	**309**	**152**	**152**

Respondents did not limit their activity only to the studied area. Almost half of all applications concerned innovative solutions in areas other than pharma and medtech.

Figure 3. Surveyed medtech entities broken down by number of applications.

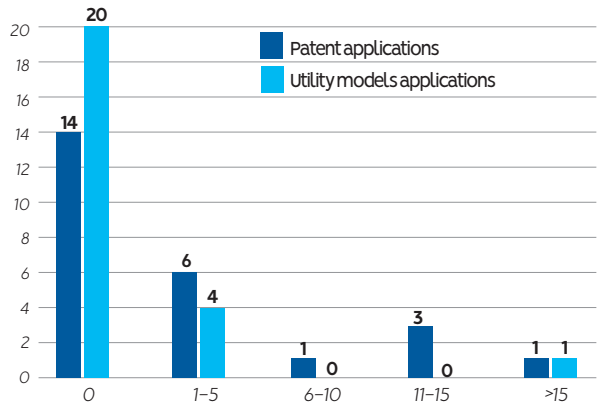


Figure 4. Surveyed pharma entities broken down by number of applications.

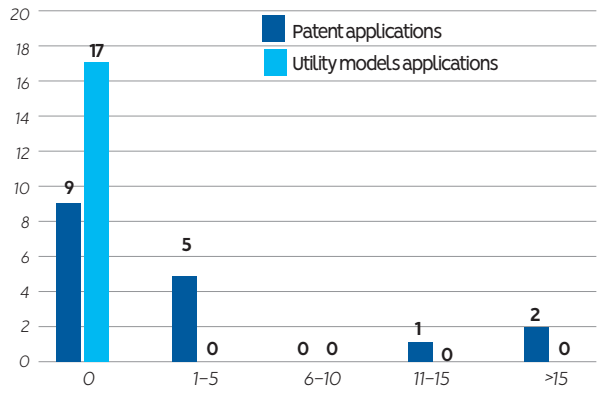


Table 2. Respondents broken down by the main activity of the company in accordance with the Polish Classification of Activities, ver. 2007.

Medtech	25	Pharma	17
2229Z	1	2120Z	9
2611Z	1	4646Z	1
2660Z	1	7211Z	5
2892Z	1	7219Z	2
3250Z	10		
4618Z	1		
4690Z	1		
4799Z	1		
6201Z	2		
7211Z	2		
7219Z	2		
8010Z	1		
9499Z	1		

The analyzed PKD is the main scope of the activity of a given company at the time of establishing the company. On analyzing the PKD of respondents, we can observe a greater differentiation within medtech sector than in pharma. In the group of the companies that deal with the production of both medical devices and pharmaceutical products, there are also such companies that set trade (46xxZ and 47xxZ) or even security (8010Z) as a focal activity.

Table 3. Main PKD for enterprises operating in the field of pharma and medtech.

2120Z	Production of medicines and other pharmaceutical products
3250Z	Production of devices, instruments and medical devices, including dental

Table 4. Respondents broken down by legal status.

Medtech	**25**
Natural person engaged in a business	**1**
European cooperative society	**1**
Joint-stock company	**10**
Limited liability company	**13**
Pharma	**17**
Natural person engaged in a business	**1**
Joint-stock company	**8**
Civil-law partnerships operating on the basis of an agreement concluded in accordance with the Civil Code	**1**
Limited liability company	**7**

Joint-stock companies and limited liability companies accounted for 43 percent and 48 percent of the respondents, respectively.

The division of respondents due to form of ownership is more diverse, but in this case we are dealing with the dominant form, that is, the property of domestic natural persons (52.4 percent). It is worth nothing that among the respondents there was one company with foreign ownership, as well as one representative of the State Treasury.

INNOVATION IN THE POLISH HEALTH SECTOR – RESULTS OF THE SURVEY

chapter 2

2.1 Understanding of innovation and innovativeness

Pharmaceutical sector

There are many connotations to the concepts of innovations and innovativeness. From the perspectives of the representatives of the surveyed enterprises, the following aspects of these concepts are important.

Firstly, **innovations can be products or services that are new on the market**. Within this, it is common to distinguish innovations that are truly groundbreaking and innovations that are improvements or refinements of established products, or in the methods of their manufacture. For the Polish pharma sector, encompassing almost only generic companies, the second understanding of innovation and innovativeness is more prevalent. Refinement innovations are associated mainly with follow-on drugs, modified in such a way that they can satisfy the unfulfilled needs of patients. Such modifications may entail improvements such as better absorption of the active substance, the elimination of preservatives causing sensitization, higher comfort of use, or better patient compliance.

Secondly, **innovations are identified as solutions which meet the criteria of patentability**, and in particular the criterion of non-obviousness within the meaning of patent law. There is a fairly common belief that if someone is able to obtain a patent for their product, it must be an innovative product.

Thirdly, the market and competitive aspects of innovation are often emphasized; in this approach, **an innovation is a product or service obtains or maintains a competitive advantage on the market**, or which is able to generate income. In this context, innovations are distinguished from ideas that are not subject to commercialization and remain only abstract concepts.

"Innovation is at the level that is needed for the development of this company"

Innovative products and services are generally recognized as being important to the market success of pharma companies, with innovation understood in the sense of both global and absolute breakthroughs and improvement or refinement solutions.

For some respondents, innovative products and services are a sine qua non condition for achieving a good position in the pharma market. However, paradoxically, for others innovative products are seen as problematic for commercialization, as they are unknown to mass clients. They claim that new products need huge information and advertisement efforts. Successful introduction of an unknown product is seen as s very difficult undertaking for SMEs, which do not have the necessary marketing power and, in particular, sufficient brand recognition. In this context, **the market for pharmaceutical products is assessed as resistant to new products.**

"Advertising sells dreams"

In the opinion of majority of the respondents, price is the most influential factor in purchasing decisions regarding pharma products. The next criterion is loyalty of customers to a given brand. The quality and efficacy of the preparations is seen as the least influential factor in purchasing decisions..

"Most people want to believe large entities with a stable market position and reputation"

The situation seems to be different in the segment of services and products offered not to end users, i.e. patients, but to other entrepreneurs. This applies to biotechnology products, intermediates used for the production of medicines, or services offered to pharma companies, e.g. in the area drug research. In this respect, the most important factors are a proven quality of products and services, extensive

experience, and the ability to offer many connected services to match needs of a wide range of recipients. Price was mentioned as the least important influencing factor.

However, price is the dominant criterion in the case of purchasing products and services according to public procurement procedures.

Taking into account types of products and services offered, the following profiles can be distinguished among the interviewed pharma companies:

A. Biotechnology companies, which are entities providing products and services in the field of biotechnology and molecular biology, including diagnostic kits, products related to nucleic acid processing, enzymes, molecular biology services, analytical services, and medicine quality control services.

B. Entities offering mainly generic products, which may be divided into the following subgroups:

» Producers of solely imitative and basic generic medicinal products, mainly over-the-counter (OTC) drugs, dietary supplements and cosmetics.

» Producers of advanced and refined generic medicinal products, including entities offering new doses of medicines, new pharmaceutical forms, products manufactured by means of new technologies. These medicines are frequently hospital or prescription medicines.

C. Entities developing innovative medicines, including companies focused on the development of new chemical entities in various clinical indications in oncology and immuno-oncology, as well as new solutions in the field of nanotechnology.

The main subject of economic activity of enterprises operating in the field of pharma is PKD 2120Z, the production of medicines and other pharmaceutical products.

Medical technology sector

The products and services offered in the medtech sector are very diverse, ranging from simple ambulatory devices, through to the operating rooms equipment, artificial tissues, and complex diagnostic technologies.

For the majority of respondents, **innovation simply means applying solutions that were previously unknown and not used** in the medtech sector. These solutions may be technical, technological or organisational.

Innovation may mean creating completely new products or improving existing products. Improving or modifying solutions may concern better efficacy, better technical parameters, environmental friendliness or the usage of new materials.

Innovation is also associated with improvements in the production or distribution of products and services.

Many respondents emphasize that the medtech field has a unique perception of innovation. On the one hand, the commercial side of the R&D activities must always be taken into account, but on the other, **the medtech sector's mission can be considered more important than that of other economic sectors**, as its goals consist of providing wider and more effective therapeutic and diagnostic options, and in improving patient care more generally.

Taking into account types of products and services offered, the following profiles emerge from among the interviewed medtech companies:

A. Entities offering products in the field of surgery and treatment, such as complex surgical instruments and devices, as well as implants and artificial tissues.

B. Entities offering diagnostic equipment, such mobile or stationary devices for early diagnosis and detection of pathological conditions, long-term monitoring systems, software for the needs of diagnostic imaging, and machines for laboratories.

C. Entities offering general medical equipment, such medical and surgical devices, general and specific hospital furniture, medical lamps, and pharmaceutical dispensers.

D. Entities offering telemedicine devices, including multifunctional telemedicine devices and entire telemedicine systems and platforms.

The main subject of economic activity of enterprises operating in the field of medical technology is PKD 2120Z, the production of devices, instruments and medical devices, including dental ones.

Respondents indicated that the following factors were relevant for purchase of products and services in the medtech sector:

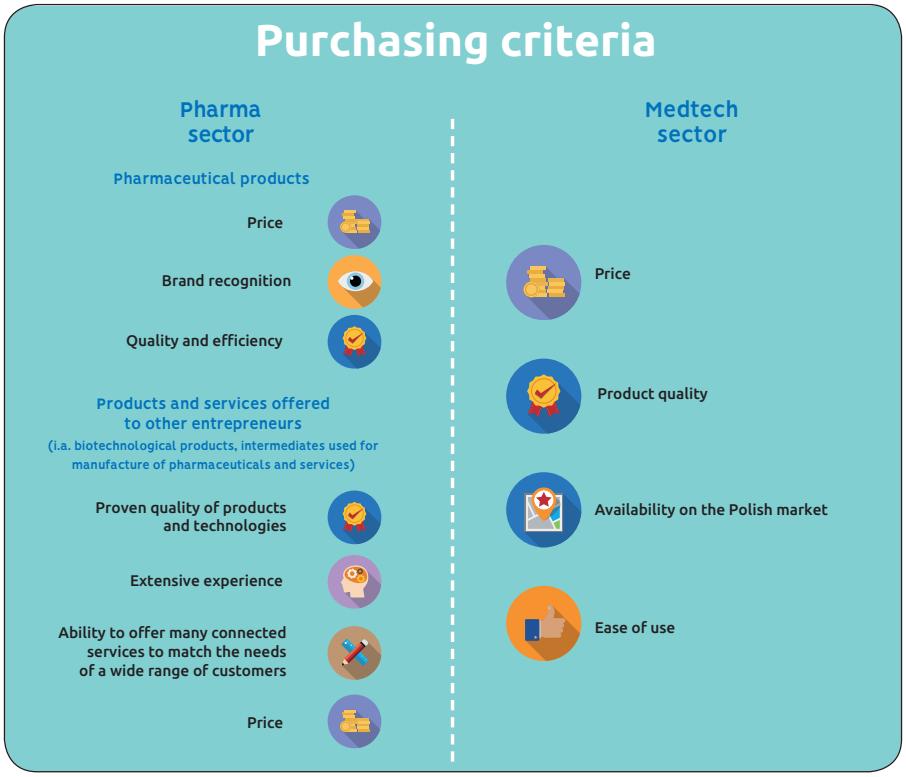
A. Price is considered crucial when making purchases in public procurement or tender procedures. The product parameters must be adapted to the requirements of the ordering party, while maintaining high quality, safety and the lowest possible price. As the vast majority of products and services in medtech are directed to private or public healthcare institutions, the price is considered the most important purchase criterion.

B. Product quality is decisive only in the case of complex technologies, such as implants, prostheses, artificial tissues, and complicated surgical instruments. In this case, the good opinion of physicians – mostly the surgeons who use these products and are responsible for the outcome of the treatment – is crucial. It seems that the physician's responsibility for devices or medtech used in diagnosis or treatment, and especially in surgical procedures, is greater than in the case of prescribing medications. The difference arises from the fact that they have no real influence on the effectiveness of the drug in the body, while they have a significant control over the use of medtech to treat the patient, and the efficacy of treatment impacts their reputation.

C. Availability on the Polish market is important as it facilitates quick responses to the needs of healthcare facilities and physicians, as well as a good access to after-sales care and services. The low operating costs and the cost of purchasing future software licenses are also taken into account.

D. Ease of use, i.e. simplicity and functionality of devices is considered important, and it was emphasized that both private users and hospital staff are more frequently choosing devices with digital displays, controlled from a tablet or phone, or voice controlled.

E. Innovativeness of products and services is rarely taken into account as a factor influencing the purchase decision in the medtech sector.



2.2 R&D activities

Pharmaceutical sector

Interviewees generally understand R&D as any kind of development that leads to the launch of a new product to the market. R&D activity is often equated with innovativeness or treated by respondents as conceptually similar. Two main types of R&D activity were distinguished by interviewees. The first type covers all activities that serve to improve existing products already on the market. The second type is aimed at developing an original, innovative product.

R&D on generics

The basis of R&D in the generic sector is to select the originating product to be developed. Based on economic and legal analyses, a specific product is selected for market introduction in a specific territorial area in which the generic version is a follow-on product.

Research begins with the acquisition of the active substance, which is analyzed in terms of physicochemical parameters. Then, the so-called "pre-formulations" occur, in which compatibility with excipients – substances which chemically stabilize the active substance and give a specific mass to the finished product – is determined. The purpose of pre-formulations is also to ensure adequate release of the active substance.

The composition of the finished form must meet the standards of bioavailability and bioequivalence with regard to the reference medicine, but it also needs to be adapted to the production requirements. The developed product must have adequate parameters, such as flowability, to enable its mass production.

In order to register a generic product, bioequivalence studies must be conducted and their results presented to the appropriate drug registration offices at the national or EU level. Bioequivalence tests and the preparation of registration documents complete the R&D cycle of a generic product.

Most generic companies try to improve the product being developed so that it is not simply a copy of the reference medicine. Improvements may relate to excipients, the shape of the tablet, the convenience of administering the drug, or the efficiency of the production process.

In enterprises exporting generic drugs, R&D must take additional factors into account. Due to the quality requirements for different climate zones, the composition of the product must be compatible with conditions of temperature and humidity, among other factors. Due to the legal requirements in different countries, there are significantly different requirements at various stages, such as carrying out bioequivalence tests.

R&D on innovative medicines

Respondents distinguished three main R&D departments. The first is medical chemistry, where potential drugs are designed and synthesized. The second is biology, which studies the effects of these drugs in the laboratory in vitro models and then in vivo models in animals. The third is development, which deals with the selection of the final molecule in a given project with preclinical development, i.e. a large-scale chemical synthesis, toxicology and the initiation of clinical trials in humans.

R&D activity is conducted in distinct departments only up to a specific phase. The largest enterprises may have extensive R&D departments that allow research on small animals, but the subsequent stages of work – in particular clinical trials in humans – are outsourced.

Bringing R&D to the pre-clinical phase can be combined with the decision to sell the innovation. The costs of carrying out clinical trials for the registration of a medicinal product are often assessed as too high for Polish pharma companies.

R&D on biological or biotechnology products is characterized by greater unpredictability. It is based on experiments on living organisms, the results of which can completely change the predictions of the schedule, budget, and substantive assumptions.

Organization of R&D

Almost all surveyed companies, both generic and innovative, have a separate R&D department and conduct R&D work in a formalized way, i.e. based on a written plan, defining the research assumptions and technical parameters of the drug to be developed. R&D is subject to periodic control of implementation.

As a rule, R&D has a fixed budget and schedule, although many respondents emphasize that they are subject to relatively frequent modifications, especially in the case of highly complex projects.

In larger enterprises, with separate departments or teams within the R&D department, the development of a given medicinal product usually requires the cooperation of three departments or teams. The first deals with the preparation of a qualitative and quantitative composition, the second is responsible for analytical work, and the third is involved in the preparation of registration documentation. Many respondents also emphasize the necessity of cooperation between employees in the R&D department and the production department.

The largest of the surveyed enterprises have separate research departments dealing, for example, solely with generic medicines or biosimilar medicines.

Most companies have financial instruments that motivate employees of R&D departments. Most often, they take the form of a bonus or promotion system. However, in the vast majority of responses analyzed, it is emphasized that the most important element motivating creative action, especially during long-term and painstaking projects, is the passion of employees and their personal commitment. In many enterprises, the stimulating factor is the possibility of parallel scientific work or dynamic professional development.

"Nothing motivates better than success"

R&D Cost

All respondents indicate their own funds, mainly derived from the earned profits, as the financial source for R&D. In addition, in the case of projects concerning the development of innovative products, all enterprises indicate that they have obtained public funds for this purpose, mainly grants from the National Centre for Research and Development (NCBiR).

Larger companies showed a percentage share of total revenues for R&D, which ranged between 7 and 11 percent.

The nominal cost of conducting R&D depends on the type of final product. In the case of generic OTC products, this cost is the lowest and amounts to about 12.000 Euro. The cost of developing a more advanced generic medicine was in the range between 50,000 and 750,000 Euro.

The cost of R&D on an innovative drug varies from 10 to 100 million Euro. This high cost is commercialization of the developed product commences before the costly final phase of clinical trials begins.

One in four of the respondents conducts clinical trials, most often in single cases of innovative medicines.

As a rule, the costs of conducting R&D in Europe are assessed as relatively low but more expensive than those carried out in Asian countries.

Duration of a drug development project

In the case of generic drugs, the majority of respondents gave the average development time as three to four years. In a few cases – mainly companies developing OTC generics – a shorter period of one to two years was indicated.

In the case of innovative products, R&D was conducted for six to seven years before the product has been brought into the clinical trials phase.

There is no uniform opinion among respondents on whether the time of developing medicinal products in their enterprise is shorter or longer than in other enterprises. The individuality of each case is emphasized.

The vast majority of surveyed enterprises never conducted research on a licensed product, although some of them expressed the desire to obtain such licenses. The vast majority of the surveyed enterprises did not conduct any research that was not directly related to the development or improvement of products, but would serve only to deepen knowledge in a given area

Cooperation and partnerships

The surveyed enterprises emphasize the interdisciplinary nature of conducted R&D and the need to cooperate with specialists in many fields. They indicate the need for knowledge in the fields of medicine, pharmacy, chemistry, physics and biology. Enterprises in the field of biotechnology added biotechnology

and microbiology to this list. Most respondents underline the importance of legal knowledge, especially related to the legal protection of innovative products and freedom to operate in the pharmaceutical sector.[1]

Entities developing new products and large generic companies conduct their research jointly with other entities. In particular, cooperation with:

A. Other companies, e.g. as part of a formalized consortium, in particular for the implementation of scientific projects.

B. Universities or research institutes, particularly for the development and improvement of products and in tests of products.

As a rule, such cooperation starts with ad hoc common activities, which evolve into formal cooperation. Some research work is reported as outsourced. Outsourcing is visible especially among entities operating in the field of biotechnology.

However, many smaller entities from the generic sector have never cooperated with universities, research institutes or other companies and do not intend to do so in the future.

The vast majority of respondents negatively evaluate the services of technology transfer centers, special purpose vehicles or innovation brokers in the science sector. They are assessed as ineffective mainly due to lack of experience in the pharma sector and unsatisfactory legal basis for their operations.

Medical technology sector

R&D activity in the medtech sector is understood as a complex process. It includes conducting basic research, and then creating a product concept on this basis of this, and then finally conducting development research to verify whether this concept has potential as a market product. This process is usually interdisciplinary and contains many partial studies. They are based on knowledge from various fields, including biology, physics and chemistry and individual branches of medicine, but also precision mechanics, electronics, computer science and utility design. In the case of medical devices, this process ends with obtaining certification.

The vast majority of surveyed enterprises have separate R&D departments, and as a rule they employ between 10 and 20 people. The exception is companies from the field of telemedicine, which have smaller R&D departments, averaging four employees.

R&D in the medtech sector is strongly formalized. The vast majority of surveyed enterprises have an ISO quality management system, containing detailed procedures and instructions for the manufacturing of medical devices, modifications of existing products and the development of new ones.

The majority of scientific and R&D ventures in these enterprises are regulated by specific schedules and business plans. Formalization of such undertakings is favored by the use of subsidies from public funds.

As a rule, **resources allocated for R&D come simultaneously from two sources**: from EU funds, most often in programs co-financing the development of SMEs, and from profits generated, constituting the entrepreneur's own contribution. In the telemedicine sector, external investors also finance R&D on individual market projects.

Depending on the complexity of the work and the final product itself, the cost and time of development can vary considerably. In the case of surgical devices, implants and artificial tissues, costs run between 250,000 to several million Euro and the duration of R&D from 1 to 10 years. The cost of developing diagnostic equipment varies between 7000 to several dozen million Euro. The time for R&D activities is the most diverse in this case of diagnostic equipment and can vary between several weeks and several years.

The cost of R&D on telemedicine products is estimated at 5,000 Euro per month. The shortest R&D period cited was several months and the longest was 10 years.

About **half of the surveyed enterprises cooperated with other commercial entities in developing joint projects**. For the most part, cooperation consisted of outsourcing services, and less frequently led to the formation of formal consortia. Overall, cooperation is rated positively. The main problem identified by the respondents is the lack of precise contractual regulations on rights, especially patent rights, with regard to the results of joint projects.

[1] *See the definition in the annex 2.*

Almost all entities cooperated with universities and research institutes, mostly Polish, but in several cases also foreign (mostly German). Cooperation was the least frequent in the field of telemedicine.

The respondents identified several problems with this type of cooperation. Universities are perceived as being too bureaucratic. The public procurement process and the verification of documents and contracts takes too much time, and the process of establishing cooperation is see as unjustifiably prolonged. Due to research dragging on and a lack of responsibility for meeting the conditions of cooperation, **projects implemented in cooperation with universities are perceived as more expensive and requiring more time.**

In addition, respondents report issues concerning differing goals for entrepreneurs and scientists. For the latter, the overarching goal is often to publish, achieve an appropriate quotation rate, and to submit a patentable technical solution. The goal of developing a mature product, fit for commercialization, is far less important. By contrast, commercialization is the most important goal for entrepreneurs.

The use of inventions developed at universities is assessed as difficult due to their low level of commercialization value.

> *"It is not easy because there are only few of those that are suitable for commercialization at these universities. Often these inventions solve a problem that does not exist."*

Usually new products are developed on the R&D scale, i.e. on a small scale. Application of the effects of these activities on an industrial scale is usually associated with huge costs and considerable time scales.

In addition, some respondents point out that universities have unrealistic financial expectations and do not show sufficient understanding of the specifics of the entrepreneur's market operations

> *"The science sector is not ready and there is no climate to cooperate with companies. Often meetings with entrepreneurs are organized, because it should be done like that. But this is not such an invitation with passion – to come, to be ready to listen to ... "*

As a rule, the services of technology transfer centers and other institutions in the innovation environment are negatively evaluated, as they are considered unprepared for their role.

2.3 Patent protection

Pharmaceutical sector

Patents and patent applications

Almost all surveyed entities have patents on pharmaceutical inventions or have submitted applications for patent protection.

As a rule, companies developing innovative medicines have patents in the product category (concerning new chemical molecules) and in the process category (claiming the methods of manufacturing new chemical molecules). As a rule, these entities are relatively new companies on the market and have only few or even only single patents.

Entities of the generic sector patent their solutions in both categories as well. New compositions of known and off-patent active substances, as well as their new polymorphic forms, are claimed in the product category. In the process category, patents are most often acquired for new production methods of known substances and their compositions, often including specific, single steps of manufacture.

Patent lifecycle management

Development of pharma inventions often takes place within the framework of formally planned projects.

This particularly applies to R&D in the innovative sector, related to the development of new chemical molecules and often part of projects co-financed from public funds.

R&D on improvements of known products are less formalized; the development of a new composition of known substances or a new method of manufacturing an already known product may take place by chance. Large entities of the generic sector emphasize that often time and cost given to solving a seemingly trivial problem means that the eventual solution became worth patenting.

As a rule, the decision to submit a patent application is taken at a very early stage of product development for fear of being blocked with further work by competitors. However, in some rare cases, interviewees said such action were not beneficial. According to such views, an applicant is, as a rule, not yet ready to commercialize the product and the patent protection period is inexorably passing. A few entities – solely from the generic sector – consciously decided to keep their solution confidential and apply for patent protection only at a later stage of R&D, based on this view.

Almost all of the surveyed entities conduct a search on state-of-the-art as standard procedure. In larger generic companies, these studies are carried out by legal departments that later develop a final patent application. Smaller enterprises from this sector commission the state-of-the-art examination to patent attorneys. Patent attorneys deal also with the overall proceedings before patent offices, which is emphasized as particularly important in the case of applications filed abroad.

Entities conducting R&D activities on innovative medicines usually cooperate with patent attorneys too, although they rarely need them to carry out the state-of-the-art search, as they usually have broad knowledge of the innovative nature of the solution being developed.

Entities in both sectors report encountering difficulties in the procedure for obtaining a patent. In the case of innovative companies, these difficulties are more often connected with the necessity of carrying out the procedure in different countries, and hence must deal with substantively different procedural requirements in particular national patent systems. In the generic sector, the main problem relates to the demonstrating the inventive step of the submitted solution and the difficulty in convincing patent office experts of its non-obviousness. The a posteriori analysis of the patentability often leads to a situation in which a given solution seems obvious to the expert. However, respondents stress that such assessments are harmful in light of an unusually broad spectrum of hypotheses and research that have to be verified in order to achieve the solution sought.

It is rare for the surveyed companies to submit patent applications jointly with other entities. If this happens, it happens either in enterprises developing new chemical molecules or in large enterprises in the generic sector. In both cases, cooperation with universities and research institutes is most frequent.

All companies that declared to have patents indicated that they applied for patent protection both in Poland and abroad. Patent protection is sought most frequently in Western Europe, the USA and Japan.

Large companies from the generic sector patent their inventions in the countries and regions mentioned above, but also in the countries of Central and Eastern Europe (CEE), the countries of the former Soviet Union or the countries of South America. Protecting their solutions abroad is essential for them, not only for the sale of their products but also because of the fact that **they license their solutions on some of the markets**. In addition, in some countries, possessing a patent for a medicinal product is an asset in the registration of medicines. In turn, in other countries, a patent protecting an improved generic medicine may have a negative impact on its registration and possible reimbursement, as it is identified with an original medicine and thus associated with a prohibitively high price.

Use of patented solutions

There are a number of regularities as regards the scope of use of patented inventions. A large number of companies developing new drugs declare that they do not use these solutions yet, as they are still in the phase of further research. Smaller companies from the generic sector, usually with only a few patents, typically use all of their patented solutions. Larger companies in this sector, possessing a significant patent portfolio, do not use all patented solutions due to the fact that specific solutions – especially those patented some years ago – are no longer considered up-to-date.

Only the largest companies of the generic sector have a formalized patent management poli-

cy. Such a policy defines the principles of developing inventions, rules for disclosing intermediate and final results of R&D activities, the policy of rewarding inventors and the principles of using inventions, as well as rules for patent search of various types, mostly verifying the patentability of an innovation, or freedom to operate with it.

Similarly, only larger enterprises in this sector have formal procedures for maintaining patents in force. However, respondents emphasized that, despite usage of such procedures, the decision to maintain or resign from patent protection is highly discretionary. The complexity of circumstances regarding the effective use of a patent means that the relevant factors are not measurable, and it is impossible to construct an algorithm that would give an answer on whether to keep the patent in force.

Decisions on maintaining patents in force seem to be even more difficult with regard to foreign markets. Respondents emphasized that **no company can afford to patent its products in all potential markets**. Enterprises that declare maintaining patent protection of their products in many countries indicated a sum of several million zloty per year, allocated specifically for this purpose. In their assessment, without making a conscious choice of protection territory and resigning from protection in countries which are less important for them, the cost of patent protection could reach 30 million zloty per year.

Benefits and importance of patent protection

In assessing the benefits of patent protection, the interviewed entities distinguished between indirect and direct benefits. Indirect benefits are observed by the vast majority of enterprises. These include: building a competitive advantage, overtaking competitors in market activities, and improving the company's credibility and its legal security.

Large enterprises – usually from the generic sector – cite the possibility of **selling patented products at higher prices as a direct benefit**. Smaller and younger entities identify direct benefits most often with profits from the **sale of company shares or the sale of a patented solution as such**. However, these practices are not frequent among the surveyed enterprises.

The surveyed entities that possess patents or patent applications usually mentioned several reasons for obtaining patent protection for their products.

"The reasons for applying for a patent? It's simple – get protection and stop others from getting protection"

The most important and most frequently mentioned reasons for acquiring patent protection are the following:

A. Securing the right to the invention against being used by others

For entities developing innovative medicines, **ensuring exclusive use of their invention is the most important reason to use patent protection**. They treat obtaining a patent as a form of protection against the theft of their IP. Obtaining a patent is also intended to create a sense of security for future activities and investments regarding the patented invention.

Obtaining a patent in the innovative sector is of paramount importance to recouping the investment in R&D. However, the development of a new drug is so costly that return on investment is only possible when the drug is sold globally. As a result, patent protection on the global market is of key importance for enterprises in the innovative sector.

B. Securing the right to use the invention against being blocked by others

Obtaining a patent for a pharmaceutical invention means that detailed information about the product itself or the method of its production is disclosed. Consequently, the essence of the solution loses its novelty, so no other entity can patent the same solution. This is essential for entities from both sectors, as it secures enterprises from having their activities blocked by competing entities. For this reason, both sectors emphasize the need to submit a patent application as soon as possible.

In the generic sector, this function of patent is cited as more important than acquiring exclusive rights to the solution. Entities from this sector are less likely to patent on a large scale abroad, and so they take into account the fact that other entities may use their solutions abroad, even

in the case of obtaining a patent in Poland. However, by obtaining a patent, they can be certain that a third party cannot block their research or market activities.

"Often, patent applications are filed to secure your right to the invention and not necessarily to the intention of attracting potential infringers"

C. Legal security

The vast majority of the surveyed entities have never participated in court proceedings concerning patent rights. Many of them emphasize that they cannot afford a court litigation. For this reason, it is crucial for them to regulate their legal situation as precisely as possible.

In addition, clarifying the patent situation is particularly important for entities developing innovative medicines that need a partner to cooperate in further development of their product or that plan to sell a patent or right to patent.

D. Increasing the value of the company

A patent is treated by innovative enterprises as an asset that can be measurably valued and which builds the company's assets. The patent portfolio of pharma companies is a key factor when applying for loans or when negotiating with potential investors.

In addition, a patent is essential in a situation when a relatively small company is aware that it is not able to develop the patented technology itself and strives to sell it. Innovative enterprises emphasize that getting a high price for a patented technology is not necessarily connected with the buyer's will to implement the patented solution. Sometimes a large player in the pharma market buys a patent only to restrict the patented drug from being placed on the market in competition with their own product.

Larger generics companies, in turn, emphasize that patents are essential when licensing the production and sale of a product abroad. **The value of a license agreement may vary considerably depending on whether the product is protected as know-how, whether it is the subject of a patent application, or the subject of one or more patents**.

Smaller companies from the generic sector admit that they have difficulties with the proper valuation of their patents. They propose that the Patent Office offers a service for the valuation of patents granted, which would facilitate taking further steps with the sale or licensing of the patent subject.

E. Strengthening goodwill towards the company

In addition to all reasons mentioned above, patents are generally perceived by the entities in both sectors as important to the company's marketing value, enhancing its credibility and reputation.

F. Giving due satisfaction to creators

"Patent is a value that determines the future of the company"

The last reason mentioned by the surveyed entities is to give due satisfaction to the inventors. Obtaining a patent is an honor for the creators, and also acts as an incentive for other researchers to work harder in pursuit of their goals.

Abuse of patent protection

According to a few respondents representing small entities in both sectors, patent protection is important for the largest and richest pharma companies – i.e. global market leaders – not only because of the possibility of achieving large profits but also because of the possibility of abusing the patent system, for example, by creating patent thickets and blocking innovation, and by using exclusive rights to initiate court disputes, even in clearly unjustified circumstances.

Lack of patent protection

A few enterprises declare a total lack of interest in patent protection, although these were the exception to the rule. These enterprises were companies

producing OTC drugs and dietary supplements and, by contrast, companies providing products and services in the field of molecular biology, mainly in the field of diagnostics.

In the first case, the companies do not carry out R&D work on the improvements of follow-on products and therefore they have no patentable material. In the second case, due to the specificity of technologies used in molecular biology, the product's lifetime in this field is estimated at only five years. Obtaining a patent and incurring its protection costs is therefore not profitable for enterprises in this area. **They strategically choose not to disclose their innovations and to protect them as know-how**.

"At present, there is no IP protection system that, in our opinion, would be effective for protecting innovation in the field of molecular biology"

Interestingly, sometimes companies that improve known products or develop innovative methods of production make a conscious decision to not apply for patents. However, in this case they decide to keep them secret. They justify such policy with a relatively high probability of refusal to grant a patent, due to earlier applications or due to lack of inventive step of the solution. In such case, a patent application involves the risk of disclosing the essence of an innovation and moving it into the public domain without providing any legal protection.

However, most of the surveyed entities point out numerous risks resulting from lack of patent protection. Firstly, maintaining a given solution as know-how is always associated with the risk that another entity will, in the meantime, elaborate the same solution, claim it and thus block the results of product development. A second risk relates to personnel mobility: the lack of exclusive rights to the key elements of research raises the risk that employees who leave the company may take this knowledge with them and share it with competitors. A third risk relates to the fact that IP constitutes an important asset and can determine the value of the company. Therefore, resigning from patenting own solutions may result in limiting the value of the company.

Almost all surveyed entities conduct research on the so-called "freedom to operate", which is an analysis of whether a planned product infringes patent rights or other IP rights. This research allows companies to determine whether a patent in force affects a product that is going to be placed on the market, when such patent protection ceases, and if it is possible to circumvent the patent. This knowledge is seen as crucial since it enables the work schedule to be planned around product commercialization, or around the potential of obtaining an own patent for the improvement of the original product. Typically, patent attorneys conduct the freedom to operate analysis; however, large generic companies may conduct it within their internal legal departments.

Only very small group of respondents does not carry out freedom to operate research. These entities do very limited R&D and have a stable number of products in their portfolio. Apart from that, they usually buy active substances from other companies and secure themselves by demanding a non-infringement declaration with the purchase.

In the vast majority of surveyed entities, there has never been a dispute regarding infringement of a patent of another entity. However, manufacturers of generic drugs admit that after receiving marketing authorization, it is normal to receive so-called "warning letters" indicating until when the patent on the reference medicine remains in force.

Enterprises that have participated in such disputes emphasize that these were isolated cases. As a rule, there is a general opinion among respondents that in the event of a dispute, it is not worth entering court. There is also a belief that domestic pharma companies do not carry out lawsuits against each other, but rather reach agreements by way of amicable resolution.

Medical technology sector

Patents and patent applications

The majority of surveyed medtech entities already have patents or have applied for patent protection. The intensity of use of the patent system varies. Some companies possess only one patent or **one pending patent application, while a few have a long patent portfolio of dozens of patents and patent applications**. On average, the surveyed companies declare having a few patents or patent applications. There is no clear-cut relationship between the medtech subfield of activity and the use of the patent system.

Entities of the medtech industry patent their solutions as both products and processes. In the first case, patents are granted typically for constructions, medical devices or new materials. As regards processes, they are connected to medical technologies, methods of manufacturing and methods encompassing algorithms in computer-implemented inventions.

The development of inventions usually takes place within the framework of formally planned projects. A few respondents underlined that even when R&D activities are planned, their outcomes may be unpredictable. In many cases, patented inventions were created within formal projects, but not necessarily followed the preliminary plan.

The procedure of applying for patents is generally assessed as complicated. In particular, properly drafting patent claims is cited as an issue, as was the necessity of multiple improvements and corrections to the claims within the patent grant procedure. Some of the respondents point out that the examination of patent application in the PPO lasts too long, while others specify the prohibitively high costs of patent procedures, especially abroad.

Most of the surveyed entities cooperate with patent attorneys, who are responsible for the state-of-the-art search. They usually conduct surveys on freedom to operate, as well as drafting the patent application and dealing with the overall proceedings before patent offices.

It is not rare for the surveyed companies to submit patent applications jointly with other entities. Most frequently, they applied for patents together with Polish universities, especially medical universities and research institutes. One company declared a patent application submitted jointly with a foreign research institute. However, some of the respondents point out that such cooperation may result in serious difficulties, particularly concerning the proportion of shares in the ownership of a patent right.

About half of the companies benefiting from patent protection also applied for patents abroad. Most often, patent protection was sought in the EU, the USA and Japan. These companies see patent protection as a necessary condition for recouping their investments. Without patent protection that is valid in the most important markets in Europe and the USA, the benefits of domestic patent protection are seen as illusory.

Respondents patenting abroad highlighted the fact that the medical services market is global. The number of Polish patients who will be recipients of a given service is very limited in comparison to the capacity to deliver the patented products or technologies. Most of the companies that do not apply for patents abroad state that the primary reason for that is lack of sufficient finances.

> *"We do not patent in every foreign market because of costs. We try to optimize costs by blocking patents only in key markets. This is cost optimization."*

Very exceptionally, medtech companies declared not to be interested in patent protection. In those few cases, they prefer to not disclose their know-how, as in their opinion there is always a risk of patent circumvention. In addition, several companies expressed caution about patenting too many solutions, as they believe it to be economically ineffective.

> *"I am a fierce opponent of patenting merely for the sake of patenting. Generally, where I do not see the potential, I advise against patent application, which will end with a Polish patent application for PLN 550, which cannot be modified later and which will reveal the essence of innovation within a couple of months"*

Benefits and importance of patent protection

In assessing the benefits obtained from patent protection, the interviewed medtech entities distinguish between indirect and direct benefits. Indirect benefits are observed by the vast majority of enterprises. Indirect benefits include building a competitive advantage, improving the company's credibility, and strengthening the company's legal security. Only a few respondents indicated direct benefits, which were connected to the sale of patented solutions.

Most of the surveyed companies declare that they use patented innovations in all or the majority of their bu-

siness activity. Many respondents indicate that they do not charge higher prices for patented products or technologies. In their opinion, the simple fact of obtaining patent protection for a product or technology is of no importance to the end customer. Thus, medtech companies are more concerned with the indirect benefits of patents.

Those surveyed entities possessing patents or patent applications usually mentioned several reasons for their need to obtain patent protection for their products or technologies. The most important and most frequently mentioned reasons for acquiring patent protection are the following:

A. Securing the right to the invention against being used by others

Companies that perceive their patented solution as a real breakthrough innovation are the only ones indicating this.

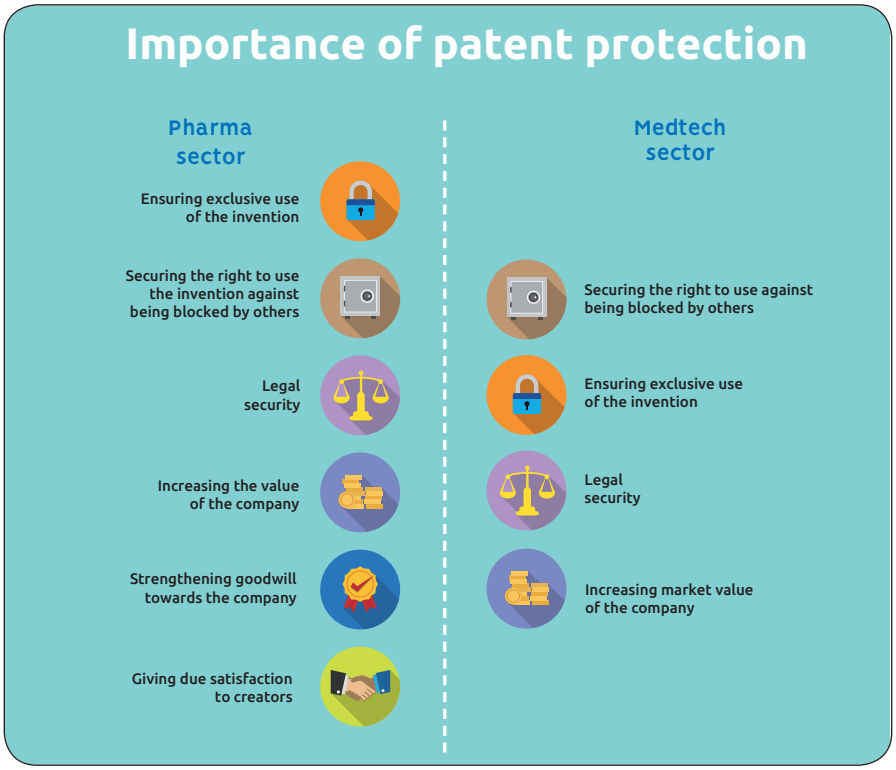
B. Securing the right to use the invention against being blocked by others

In general, this function of patent seems to be more important in the medtech sector than obtaining exclusive rights to an innovation. Obtaining a patent for an invention means that detailed information about the product itself or the method of its production is disclosed and, consequently, the essence of the solution loses the novelty so that no other entity can patent the same solution. This is essential for the surveyed entities, as it secures enterprises against being blocked in their activities by competing entities. This is crucial reason for seeking protection, particularly for companies that intend to develop their inventions into the more sophisticated versions.

C. Legal security

A minority of the surveyed entities participated in court proceedings concerning infringement of patent rights. A few of those disputes ended with invalidation of the patent in question.

> *"If we did not care about patent protection, we would not have found sources of financing to date. It would also be unlikely to bring investors to the tasks still ahead."*



D. Increasing the market value of the company

The patent portfolio of medtech companies is of key importance when applying for loans and when negotiating with potential investors. Many respondents indicate that patents are important to prove the credibility and good reputation of a company. They seem to be necessary in negotiations with foreign partners. Most respondents believe patents are crucial for initiating cooperation with distributors of medical products and services in foreign markets. The medtech sector generally sees patents as prestigious and typically uses them for enhancing marketing strategies. Medtech patents are often paired with scientific publications in domestic and foreign specialist journals, which also enhance the market position of a company. A relatively high number of respondents say that patents are valuable for proving the experience of a company and its capacity for future R&D projects, such as those funded by domestic or European grants.

On the other hand, many respondents stress that patents alone cannot generate prestige and goodwill. It is necessary to undertake marketing activities, including expensive undertakings such as professional events, scientific congresses, forums and meetings. Only huge enterprises are able to afford this kind of promotion.

Abuse of patent protection.

Respondents in the medtech sector do not report cases of abuse of patent protection.

2.4 Protection of intellectual property

Other IP Protection

Trademarks and industrial designs are the most commonly used alternative forms of IP protection. The entities specializing in the sale of OTC drugs emphasize that trademarks are of key importance because they build the brand and customers' attachment to the product. Customers usually base their purchasing decisions for non-prescription drugs on television commercials, information obtained on internet forums, or on the grounds of a pharmacist's advice.

A similar position is taken by entities in the field of molecular biology and biotechnology. For their services and products, trademarks, branding and the designation of the company are crucial, since they enable them to effectively promote their products and distinguish themselves from their competitors.

Companies developing new drugs do not own IP rights apart from patents. This is due to the fact that their products are still in the R&D phase and are not offered for sale.

> *"The social awareness of the Polish society is also growing very fast when it comes to the intellectual and intangible values. Poland is currently chasing Western countries, trying to catch up and realizing that IP is one of the most valuable sources of wealth for companies, countries and individuals."*

However, IP rights are perceived by the vast majority of surveyed companies as beneficial for the development of enterprises. Respondents emphasize that **the most important benefits include increasing the value of the company in relations with investors or banks, and strengthening the company's credibility with the NCBiR, National Science Centre (NCN) and other government agencies when applying for grants and subsidies**.

In the general opinion of respondents, IP is not important for acquisitions and mergers. A very small group of respondents does not have any IP rights and does not pay any attention to them at all.

> *"It seems to me that if today someone really wants to steal IP, it is impossible to protect against it"*

Pharmaceutical sector

The Polish IP system is seen as convergent with the European system to a large extent.

Many respondents point out that the IP protection system in Poland is cheap compared to Western European countries, especially in relation to the costs of court proceedings and legal services. However, entities in the area of biotechnology and molecular biology expressed a different view. In their opinion, their field is so highly specialized that it is difficult to find affordable professionals among Polish patent or legal attorneys.

In the opinion of the majority of surveyed enterprises, **the main problem with the Polish IP protection system is the lack of specialized courts**. Respondents emphasize that IP cases are dealt with by district courts, in which judges are often unprepared to adjudicate on complex patent cases. As a result, the proceedings before the courts are unduly prolonged and judgments submitted in IP cases are quite unpredictable. Many respondents assess this system negatively when compared with more mature jurisdictions, such as Germany or Britain.

Problems in the substantive law of IP, as indicated, concern interim injunctions, the interpretation of the so-called Bolar exception, and the lack of manufacturing waivers in the regulation of SPCs.

In the view of the respondents, the Bolar exception should be regulated by the Polish Act on Industrial Property in a more precise manner. This exception should explicitly cover offering, importing, selling and using samples of the patented substance for the purposes of market authorization procedure.

With regard to SPCs, respondents proposed that manufacturing waivers should allow for production of the SPC-protected pharmaceuticals when they are intended to be exported beyond the EU. **This legal mechanism would enhance the competitiveness of the generic industry in Europe against their competitors located in countries with no SPCs**.

Respondents point to the excessive length of court proceedings, often lasting for many years, as the reason for their appreciation the so-called "bifurcation" system, in which courts decide on patent infringement and the patent office decides on patent invalidity. However, the prevailing opinion holds that specialized courts should be set up to deal with both types of cases.

A small group of respondents points to problems with timely handling of proceedings in the PPO. For example, they indicate that the patent invalidation procedure can last for several years and consider this unreasonably prolonged.

Finally, the initial years of the SPC system in the PPO are subject to critique. Many generic companies believe that many of the SPCs granted during this period should not have been granted at all.

Most respondents do not identify IP abuses in the Polish pharma market. Larger generic manufacturers indicate specific abuses, mainly concerning disputes before courts, which may be initiated by producers of innovative drugs in objectively unjustified cases. Infringement proceedings can take many years, which in turn may result in the elimination of a given product or the entire company from the market.

They also mention that innovative drug producers may refuse to sell a sample of an active substance needed for the generic registration procedure, even when it was impossible to purchase this material from another manufacturer. According to respondents, the reason for refusal is the desire to delay the bioequivalence study of the generic product.

Medical technology sector

Respondents do not indicate differences between standards of IP protection in Poland and in Europe.

However, some respondents' comments concern business practices in this area. They believe that more importance is attached to patents and IP protection of products in Western Europe and the USA. They also note that companies in these territories conduct careful observations of products and services proposed by competitors and have a greater understanding of the latest trends and technologies. International fairs, exhibitions and scientific conferences play a more important role there than in Poland.

Regarding the operation of the EPO, only a few of the respondents complain that it works too slowly and assess the European patent system as ineffective.

"It is incomprehensible to me that the grant of a patent lasts five years, even taking into account some very complex technologies."

> *"Simply now, in practice, every digital device that performs more complex operations, such as data processing, implements a specific algorithm. Applicants pretend that it is a device and patent law, and the Patent Office – Polish or European – pretends to get it and grant a patent, but there is some fiction. The patent office in the States is more user –friendly, so to say."*

Entrepreneurs in the field of telemedicine emphasize that patent law in the USA is much more suitable for their solutions. US patent law is seen as more flexible, especially regarding the patentability of software solutions.

2.5 The role of IP for innovation

Pharmaceutical sector

In the pharma sector, opinions on the impact of IP rights on innovation are very diverse.

Large enterprises developing refinements of known drugs, as well as a few entities developing innovative medicines, express the view that the IP protection system has a positive effect on innovation. These enterprises consider innovation to be something worth protecting, and so they view IP protection as necessary. The cost of launching a new product on the market – especially one had to overcome major technological barriers – is very high, and there is also a high possibility that such product will be copied once they are placed on the market. Without IP protection, the development of such products would be economically unjustified.

Interestingly, about half of respondents in the pharma sector see the impact of IP on innovation as neither positive nor negative. They express the view that IP secures a certain balance of interests in the market and has a neutral impact on innovativeness levels in enterprises.

In this context, respondents emphasize that the Polish market is a specific one, in which maintaining solutions in secrecy and protecting them as know-how plays a very important role. Among smaller generic companies in particular, the common perception is that keeping solutions confidential is the most effective way to protect them.

In the case of small enterprises, **there is also anxiety about the economic barriers that make IP protection inaccessible**. Respondents indicate that high costs make it extremely difficult to decide which products should be secured with IP rights and, if so, at what moment. They emphasize that large entities in both sectors have sufficient financial resources to create a protective barrier around their solutions from the very beginning of their development.

Medical technology sector

The vast majority of the surveyed companies own IP rights apart from patents. Most often, these are trademarks, industrial designs or utility models. Some of the respondents mentioned all these rights together in relation to the products and services offered. The **greater diversity of IP rights with respect to the medtech sector** compared to the pharma sector reflects the greater diversity of products and services on offer in the former.

Trademarks play a very important role in the medtech sector. Almost all surveyed companies have one or several trademarks or are in the process of developing them.

The majority of medtech entities believe that trademarks are essential for promotion and buildin a good reputation for their company. Many respondents claim that without a trademark it is impossible to distinguish their own flagship products and services from those offered by competitors. This distinction is necessary not only in marketing and sales activities, but also in R&D and educational activities.

Protection of design plays a significant role as well. Many of the respondents emphasize that products aesthetics and unique designs are just as important as technical solutions. In particular, this applies to medical and diagnostic equipment.

Utility models and patents are assessed as necessary to protect against product copying, especially when the construction or structure can be easily replicated. This is often the case, as medi-

cal devices and technologies are usually presented in detail in the accompanying information materials and on supplier websites.

In the case of relatively simple products protected by utility models or industrial designs, entrepreneurs are aware of the danger of manufacturing a product that is very similar to the protected product even if it does not violate industrial property rights. However, in many cases, **they are of the opinion that the low market price of their products discourages potential imitators**. In addition, obtain the necessary medical device certification constitutes an additional barrier to introducing an imitation product to the market.

The overwhelming majority of respondents emphasize that it is more sensible to protect their products with industrial property rights, rather than as trade secrets.

The situation is different in the case of enterprises that deal with telemedicine. The respondents emphasize that these solutions – based on software and algorithms for biomedical data analysis – cannot be properly protected under any of industrial property rights, and so their solutions remain company know-how.

"We operate in a legal environment that makes it impossible to patent our telemedical platform. We are in a permanent risk that someone having proper means will be able to copy our technologies unpunished"

In the vast majority of surveyed enterprises, IP is seen as having no impact on the innovation in the sector. The IP rights are generally perceived as an element of the competitive struggle between entrepreneurs. However, there are no reports of abuse of the IP rights system.

"You can see that these industrial property rights have become an element of a competitive fight, but a really deferred one. Companies do not use the rights now, they will only use it once someone gets into their detriment, and they will be large enough to enforce these rights"

2.6 Instruments of public support

Pharmaceutical sector

Within the pharma sector, the fields of biotechnology and molecular biology are seen as creating the greatest development opportunities for Polish companies, as such are seen as worthy of support from the Polish government. This holds true in relation to both innovative medicines and generic medicines, or so-called "biosimilars". It is believed that innovations in these areas does not require huge financial investments, such as those needed to develop and commercialize innovative small molecule drugs.

With regard to biosimilar drugs, follow-on activities are more ambitious and demanding in comparison to manufacturing of "ordinary" generic drugs, as they are bioequivalent to small molecule medicinal products. Such activities are assessed as a good starting point for further development of the generic industry in Poland.

With regard to the division between the generic and innovate sector, the majority of respondents believe that the Polish government should support the generic industry. In their opinion, **there are well-understood economic and social reasons that these drugs should be manufactured in Poland, taking into account any situations of sudden crises resulting in need to satisfy the domestic market.**

Within the generic industry, respondents indicate that medicines for the treatment of geriatric diseases – such as neurodegenerative diseases, cardiovascular diseases and cancer – are particularly worthy of attention and government support.

Few companies developing innovative medicines are of the opinion that it is necessary to encourage development of the innovative sector, in particular in the area of oncology.

In the opinion of majority of the interviewed entities, the available public support is not sufficient to incentivize R&D activities and enhance the domestic pharma industry. They point out that Polish companies, employing Polish scientists and paying taxes in their homeland, deserve stronger support. Many of the respondents indicate that foreign entities are often favored in drug reimbursement procedures due to "political correctness".

According to the majority of the surveyed entities, the government should support domestic industry through a considered policy of reimbursement. Many respondents have strong hopes for the new "medicine policy of the state" and believe that future modifications of the Polish reimbursement law for medicinal product should take into account R&D activities conducted in Poland, and prioritize opening and maintaining manufacturing centers there.

Many of the surveyed entities emphasize a feeling of social responsibility with regard to the lack of certain medicines on the market, among other issues. According to the respondents, Polish companies usually distribute their products on the domestic market in such situations, even if it means losing the higher margin they would obtain abroad.

Another proposal is the simplification of excessively bureaucratic procedures, evident primarily in applications for and settlements of co-financed research projects.

"From the point of view of the grant, it would be ideal if all biological reagents would have one category and would be ordered from one supplier... the specificity of the research is that firstly it cannot be predicted at the beginning of the project what will be bought in half a year, because the research is going on in such different directions"

In addition, respondents suggest modifications to the Polish Law on Industrial Property with regard to eliminating some of its more archaic mechanisms, such as the necessity of a legal interest in the procedure for invalidation of patent.

Many of the respondents appreciate tax benefits related to conducting R&D, but at the same time emphasize that the officials who supervise these tax reliefs treat them with high levels of suspicion.

Larger companies point out that many research grant programs are directed only at SMEs. **This means that the largest Polish companies are left without public support** even though they are small when compared to their competitors on the global market.

Another perceived problem concerns the approach taken by the so-called "Polish Smart Specializations" and the criteria of assessment used in the research grant programs. In the opinion of many respondents, **this approach used to be more focused on commercialization possibilities, whereas now it is definitely more concentrated on basic research**.

"First assessments of the grant applications were more pro-business, but later experts started to draw their attention to citations, not to the eligibility of using the outcomes of the projects in a commercial way."

Yet another problem concerns the **lack of coordination between the policies of various governmental agencies**. This can be observed in the case of dietary supplements: on one hand, they fall under the Polish Smart Specializations, but on the other, their value is contested by health authorities. Respondents emphasize that policies, legal mechanisms and financial support in certain segments of the pharma industry should be logically and coherently connected.

The final and very general suggestion is connected to education programs. Respondents point at subjects like biology, chemistry, and physics are taught purely theoretically and there are no laboratories at primary and secondary schools, and even in higher education, lab work is not emphasized. **This overly theoretical approach means that pupils and students do not develop an interest in science**.

Medical technology sector

Respondents point out that many segments of the medtech sector are creating serious development opportunities for Polish companies and should be supported by the Polish government. These segments include new technologies in diagnostics, telemedicine and IT in medicine, biomedicine, implants and transplants and medical devices and services for an aging population.

In the prevailing opinion among respondents is that the Polish medtech sector should be strongly supported, especially given the export opportunities it creates. Particular attention should be paid to telemedicine and IT in medicine. Due to the relatively low cost of developing solutions in this field – especially the low labor costs and the high level of specialist skills in Poland – this sector is seen to have a huge development potential.

"Biotechnology, biomedicine, as well as information technology or electronics are those areas that can determine the development of an innovative economy. These are industries that are developing very fast today, but these are also the areas where there is always room for completely new solutions."

Most respondents believe that entrepreneurs from the medtech sector have opportunities to obtain support for pro-innovation activities. The respondents who do not see support from public institutions, or consider this support insufficient, remain in the minority.

The interviewees gave a positive assessment of the subsidies that facilitate the acquisition of patents in Poland and abroad. However, many respondents indicate that due to the high costs of patent protection, existing programs should be supplemented with financial support for maintaining patents in the initial phase of product commercialization. In addition, many negative comments concern the fact that current subsidies programs are focused on basic research, and there is a lack of support for product implementation.

For many companies, another problem lies in the lack of coordination between various government agencies. **There is no clear information about the priorities of government support in the health sector**. These priorities often change or are not properly made public. This situation inhibits long-term actions by entrepreneurs.

"If we organize various targeted financing, for example as part of the National Center for Research and Development, and decide that we will support certain industry sectors or specific segments within these sectors within the market strategy, support in this area should be coordinated. In Poland, it still works very chaotically. The activities of the National Center for Research and Development are not correlated with the activities of the Medical Technology Assessment Agency, the Ministry of Enterprise, the National Health Fund or other government agencies."

An important problem for entrepreneurs is the lack of a clear, well-defined procedure for introducing new medical technology to the market.

"There are no legal regulations allowing for the determination of a predictable and defined path of introducing new technology to the market. If Poland spent public money on the development of this type of technology, but at the same time created a path that would allow the implementation of this technology on the market and this money would be allocated in advance to validate such technology through e.g. clinical tests, then – having 40 million people with us – we would be able to create great solutions. It could be a base for later foreign expansion if it was well coordinated."

"We should enable and support the path of placing products on the market. Today, to achieve global success, you need to verify a business hypothesis or product prototype. In a very difficult and demanding market, it is not easy to introduce innovations, and you do not have to enter it very widely and globally, but you have to test it on the market and observe market reactions."

In addition to the introduction of medical technology to the market, **it is problematic to introduce new, innovative products into the reimbursement lists**. The reimbursement policy in the medtech sector is seen as operating within the framework of old, rigid, unmatched product groups.

Another reported problem is connected to the attitude of public administration officials, who tend to execute their controlling competences in an unduly burdening manner. There is no established practice of officials who advise and help. The issue is also associated with the problem of unjustified suspicions of bribery. Often, any contact between officials and entrepreneurs is treated as an attempt to exert unofficial pressure on administration employees. This atmosphere makes it difficult to conduct talks and search for constructive solutions.

"Stop saying that we support innovation and start to support innovation. Let innovation and innovativeness not be just meaningless slogans. I am afraid sometimes, as I hear some statements of policy makers that talk about innovation and maybe even do not know what it means."

As for changes in Polish law, respondents indicate the **price of products and services as should not be the main criterion for their purchase** under Public Procurement Law. In addition, it is suggested that **R&D costs should qualify as tax deductible**.

Respondents also have high hopes for a **transparent and stable reimbursement law**. Entrepreneurs in the field of telemedicine expect **changes in the law regarding the circulation of electronic prescriptions**.

One of the problems raised by the respondents is the **lack of practical preparation of graduates in technical faculties** and the lack of legal mechanisms that allow the training of young employees, with some benefits for entrepreneurs. Such mechanisms should take into account the fact that the practical training of young employees is a time-consuming and risky task, and that apprentices often leave Poland in search of better-paid work. The employees' training should therefore be combined with some form of guarantee of a fixed-term of work with entrepreneur who is providing the training.

Entrepreneurs emphasize that huge sums are allocated from the state budget and from EU funds for R&D projects, which often yield only trivial results. In their opinion, the only result of such projects is a few articles in specialist journals. However, **research results contribute to commercialization of new, innovative products and services only rarely**.

In addition, many respondents observe that universities do not care about optimizing grant expenditure. They are not obliged to pay their own contribution and they often incur project costs in an ineffective and uneconomical way. There is a common belief that entrusting the same funds to entrepreneurs – instead of universities – would lead to better management of those funds.

"We are spoiled with big money, because everyone says there is no money for research. They are powerful – there are often million projects. And there is an excess of form over the content, often these words –R&D activities – are abused, especially at universities (...)"

Respondents indicated that cooperation with universities could be improved with the introduction of an industrial doctorate, i.e. a scientific work that combines basic research with its implementation.

chapter 3

SUMMARY AND CONCLUSIONS

3.1 Summary

This part presents summaries of particular subchapters of the analysis. It refers to respondents views and opinions and does not include the author's ones.

Understanding of innovation and innovativeness

Respondents from the Polish pharma sector understand innovations in a broad way, covering both breakthrough and refinement medicinal products. This differentiation between the two embodiments of innovation is very intuitive, but it corresponds well with the regulatory system for marketing authorization in Poland and in the EU, involving innovative (reference) medicinal products and generic medicines. The first ones are authorized for the market on the grounds of full clinical and preclinical data, whereas the second are authorized by reference to the data of the innovative drugs (see definitions in Annex 1).

This perception of innovation is oriented towards marketing authorization. The other two main views of innovation derive from patent-oriented and competition-oriented perspectives. Within the first perspective, innovations are equated with patentable solutions. Within the second, innovations are associated with market blockbusters and underlying competitive advantage.

Respondents from the medtech sector perceive innovation as the application solutions that were previously unknown or not used. These solutions may be technical, technological or organizational. For most products and services provided by enterprises from medtech sector, market access is not subject to the same rigorous requirements as pharma. Hence, there is no dichotomy between innovative and generic products as is the case with new medicines.

The areas of economic activity are more diversified in medtech than in pharma. The purchase factors are also more diverse in medtech. Due to regulatory verification of the safety and efficacy of all medicinal product being launched to the market, their quality is assumed as given and as a rule does not constitute a criterion for purchase decisions. Innovation of products or services is a decisive purchase factor only in highly innovative biotechnology companies. For the remaining pharma companies, as well as for medtech companies, the most important factor in the purchase decision is price of products and services.

R&D activities

There are many differences between pharma and medtech with regard to R&D activities. In the pharma sector, levels of R&D complexity, formalization, duration and cost depend on the kind of product being developed, with clear differentiations between generics, improved generics and innovative products.

The R&D activity around follow-on generics is largely uniform and less complicated. In the case of refined or improved generics, R&D may have various starting points, be more or less formalized and lead to innovative solutions to different extents and of various kinds. However, in both cases, R&D aims at proving the bioequivalence between the generics and the originators. The most complex R&D activities relate to innovative medicinal products, as the process is strictly formalized, scheduled and monitored. The costs of R&D in the three pharma categories are 50,000 zloty for generics, 50,000 to 750,000 zloty for refined generics and 10 to 100 million zloty for innovative drugs.

The characteristics of R&D in the medtech sector are not subordinated so clearly to products or services categories. The cost, duration and complexity of R&D depends very much on conditions of individual cases. The ISO quality management system means that the R&D is strongly formalized throughout the whole sector.

There are some similarities between the two sectors. They are observable in the interdisciplinary character of R&D comprising many fields of science, simultaneous usage of own funds and public subsidies as R&D funds, as well as in the frequent cooperation of the medtech companies with universities and research institutions.

Patents and other IP protection

Companies from both sectors protect their IP with rights other than patents. Protection of trademarks is common in both sectors, and utility models and designs play an important role in the medtech sector.

Trademarks are important, especially for manufacturers of OTC drugs and medicinal devices, as they build the brand and customers' attachment to the product. Utility models and designs are seen necessary to protect against copying of medical devices, especially in case of products that are relati-

vely expensive but have a structure or construction that may be imitated easily.

Almost all companies in both sectors have patents for their solutions, granted for both products and processes. All patenting pharma companies search also for patent protection abroad, whereas foreign patents are important only for about half of the medtech companies.

Pharma companies submit their patent applications independently, without co-applicants. For medtech companies, it is relatively common to submit patent applications jointly with other entities, especially with Polish universities and research institutes.

Entities of both sectors report encountering difficulties in the procedure for obtaining a patent. For larger pharma companies, these problems are mostly related to carrying out the procedure in foreign countries. For smaller ones, the main obstacle is proving a sufficiently significant inventive step. For medtech companies, the biggest barriers are drafting patent claims, the necessity of multiple improvements and corrections of the claims.

The direct benefits of patenting are reported by only few pharma and medtech companies – mainly the largest ones – as resulting from licensing the product, the sale of shares or the sale of a patent. The indirect benefits of patents are seen as more prevalent. These encompass building a competitive advantage, overtaking competitors in market activities, and improving the company's credibility and legal security.

The reasons of applying for patent and IP protection are similar in both sectors. The most important reason cited is securing the right to use the invention without being blocked by others. Securing the exclusive right to the invention is only of secondary importance. Other common reasons for applying for patent protection include: creating legal security, increasing the value of the company, strengthening goodwill towards the company, and proving experience.

Very few companies declared that they have no interest in patent protection. These are either companies with very low or very high levels of innovation. The former are manufacturers of follow-on drugs and the latter are companies from biotechnology or molecular biology fields.

Overall, IP protection in Poland is assessed positively by both sectors. However, there are a few reservations concerning particular factual and legal aspects. Even though the IP protection system in Poland is cheaper than in Western European countries, many companies still feel that they cannot afford to use this system to the extent that they would like. The postulated legal changes concern both substantive law and procedures before courts and the patent office. With regard to the former, there are problems with the Bolar exception and SPC manufacturing waiver. The latter concern the lack of a specialized patent court, as well as the excessive length of court proceeding, and legal interest as the initiating premise of a patent invalidation procedure.

Legal standards of IP protection in Poland and in Europe are perceived as similar. However, differences are found between the IP law in Europe and in the United States. The latter is seen as more patentee friendly, especially in the area of software inventions.

Discrepancies are observed in the business approach to IP in health industry in Poland compared to Western Europe and the Unites States. The foreign industries are characterized as having more mature approach, relying more on protection of innovation through IP rights, setting and chasing new trends in innovation, and having a better understanding of role of innovation in competitiveness.

Opinions on the impact of IP rights on innovation differ depending on sector. For the largest pharma enterprises, the IP protection system has a definite positive effect on innovation. However, half of the respondents from this sector assess the impact as neutral. This view also prevails in the medtech sector.

Instruments of public support

Within the pharma sector, the fields of biotechnology and molecular biology are seen as creating the greatest development opportunities for Polish companies. These fields are supported by the Polish government in relation to both innovative medicines and generic medicines. In the medtech sector, the fields seen as worthy of support include new technologies in diagnostics, telemedicine and IT in medicine, biomedicine, implants and transplants, and medical devices and services for an aging population.

Government support of innovation is assessed as more successful in the medtech sector than in the pharma sector. However, there many observations and proposals for changes across both sectors.

EU funding programs are generally available for companies in both sectors, except largest pharma companies, which view this a huge competitive disadvantage.

EU funds are spent mostly on basic research, whereas the health industry is more interested in grants for commercialization of products and services. Grants supporting the acquisition of patents in Poland and abroad are assessed positively. However, respondents believe that existing programs should be supplemented with financial support for patent maintenance during the initial phase of product commercialization.

Reimbursement policy is perceived as one of the most powerful instrument of support that can serve interests of the domestic health industry, especially in terms of privileges granted to entities with R&D and manufacturing centers in Poland. Companies from the medtech sector proposed changes in the reimbursement law with regard to the introduction of new innovative products into the reimbursement lists. In addition, respondents suggest modifications in the Polish laws on public procurement law, tax, pharmaceuticals, and medical devices. It is obvious that pharmaceutical and reimbursement law is crucial for pharma companies. The medtech sector is not equally attached to it and emphasize importance of other laws too.

The lack of policy coordination between various governmental agencies is seen as huge problem in both sectors.

Companies from both sectors are concerned about education programs, which they view as too theoretical and lacking the hands-on approach. The medtech industry in particular needs educational instruments that allow for the practical training of graduates in technical faculties.

3.2 Conclusions

Understanding of innovation and innovativeness

Innovation in the health sector does not have a single intuitive meaning. Instead, it encompasses three various notions, namely: of an innovation sensu stricto; of an invention; and of an original or reference product within the regime of pharmaceutical law. However, both in the legal and economic sciences, each of these notions has its separate meaning.

First of all, innovations must be differentiated from inventions. In general, an invention refers to finding or creating a new piece of knowledge, whereas innovation assumes transforming it into a marketable product.[1] In more precise terms, the notion of invention covers a technical solution which – in order to be patentable – must be new, non-obvious and industrially applicable. Innovation refers to the introduction of a new product or technology in a commercialized form on the market.

The notion of innovation in the pharma sector is also not the same as that of the original or reference products. The concept of an original medicinal product does not have a statutory definition; original products are commonly understood as medicines authorized based on a full registration dossier. The concept of reference product is defined in Directive 2001/83/EC and is broader, covering not only medicines authorized for the first time based on a full registration dossier, but also products authorized on the basis of the so-called "well-established medicinal use". Therefore, not all reference products are innovations.

Innovations in this sector may also take the form of secondary improvements or refinements to known medicines and, as such, may be authorized for the market as generic medicinal products. Therefore, not only original products may be innovative.

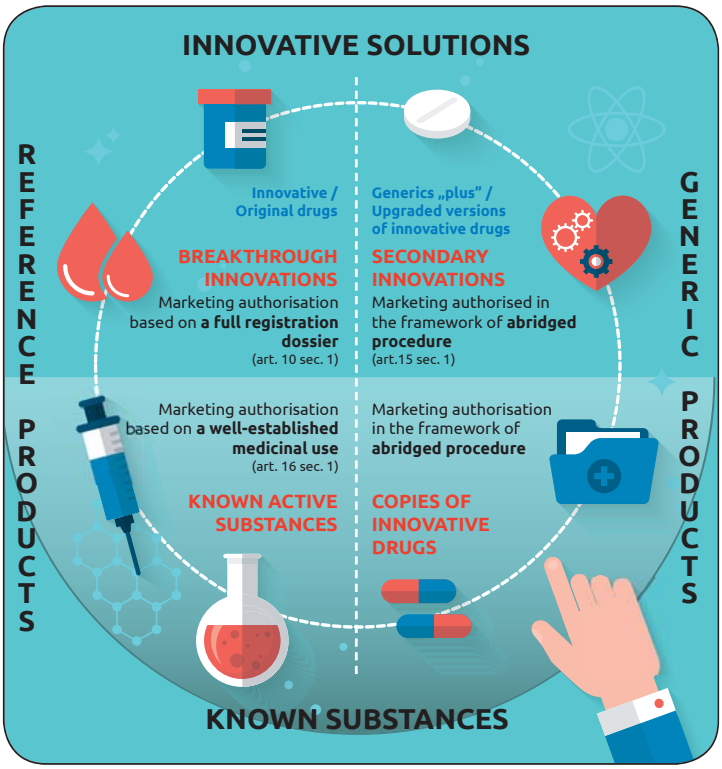
Innovation in the Polish health sector

Polish pharma sector is mostly generic. So far, there are no companies that introduce original medicinal products on the market.

However, this does not mean that there are not any research-based pharmaceutical companies. A few companies conduct R&D on innovative medicinal products in the area of oncology and immune-oncology. The model of commercialization of their R&D activities assumes that the rights to the examined products and results of the tests done so far will be sold to big pharma companies. There are no strong hopes for Polish innovative medicinal products within the coming years.

In contrast, the generic industry is developing secondary pharmaceutical innovations, i.e. improvements to known medicines or improvements in manufacturing methods. These include new formulations, modified doses or routes of administration, and reformulation of excipients.

[1] *See, e.g. W. Kingston, Why Patents Need Reform, Some Suggestions for It, in C. Arup, W. van Caengegem, Intellectual Property Policy Reform: Fostering innovation and Development, Cheltenham 2009, UK and Northhampton, MA, USA, p. 22; P. Dasgupta, The theory of Technological Competition, in J. Stieglitz, G. Matthewson, New Development in the Analysis of Market Structure, Cambridge 1986, pp. 519–548.*



In addition, biotechnology companies are working on molecular biology products and technologies, such as isolation or amplification of nucleic acids.

The medtech industry is more diversified in terms of innovation. Innovative medical products and technologies – both breakthroughs and improvements – are patented and introduced to the market.

The most groundbreaking innovations include artificial hearts, bone substitutes, traumatological implants and artificial tissues. Other examples of innovation in this sector include neurophysiology diagnostic equipment and devices for an early diagnosis of breast cancer, as well as stents and biodegradable dressings. Relatively, many Polish companies are working on highly innovative telemedicine devices and IT solutions for medicine.

Within the pharma sector, the biotechnology and molecular biology subfields are seen to be creating the greatest development opportunities for Polish companies and worthy of governmental support, with regard to both innovative medicines and generic medicines. Within the generic industry, these are medicines intended for the treatment of geriatric conditions, such as neurodegenerative diseases, cancer and cardiovascular diseases.

It is important to note that R&D activities in the pharma industry shift from chemical small molecule drugs into biologic large molecule medicines. It is believed that innovations in these areas do not require the huge financial investments that are necessary in the development and commercialization of innovative small molecule drugs. Such a belief may be based on the assumption that there are not as many failed R&D activities in biologic drugs as there are in the development of new chemical drugs. The more prosaic explanation of this conviction is that biotech start-ups need not carry the costs of accumulated failures, as larger pharma firms do, which makes the average cost of new biologics lower.

As regards biosimilar drugs, their development is more ambitious and demanding in comparison to the production of small molecule generic drugs. Such activities may constitute a good starting point for further development of the potential of pharma industry in Poland.

In the medtech sector, the biggest potential of innovation lies in the following areas: new technologies in diagnostics; tele-medicine and IT in medicine; biomedicine, implants and transplants; medical devices and medical services for an aging population.

Due to extraordinarily high costs for the development of original medicinal products, the medtech sector creates more and better chances for breakthrough innovation in Poland.

Patents and IP rights as stimulators of innovation

For both of the surveyed sectors, patents serve primarily as a defending tool, securing right to an invention against being blocked by others, and only secondarily as a tool for securing exclusivity. This may be interpreted as a sign of immaturity in the innovation field of the Polish health industries.

Polish companies, as a rule, do not elaborate any sophisticated patent strategies, neither active nor passive. Active strategies – which are usually created for strong and broad protection of breakthrough innovations and comprise elements such as patent thickets or ever-greening patents – are not relevant for improvement innovations and are far too expensive for generic companies. The surveyed companies have very basic concerns when it comes to applying for patent protection, such as the most appropriate moment to apply for a patent and the territory in which protection should be sought.

Passive strategies – which intend to use a patented solution of third parties – are not very common either. It is rare for Polish companies to acquire the right to a patented solution or to circumvent a patent, risking infringement.

At the current stage of development of the domestic health industries, legal security seems to be a higher priority than more potentially lucrative but hazardous patent strategies.

Patents stimulate innovation in the medtech sector, allowing companies to recoup investment on R&D activities. However, this is seems to be only partially true for innovation in the Polish pharma industry.

Indeed, due to the high costs of commercialization of new medicinal products, the patent system is believed to be a necessary stimulus for innovation, particularly in the research-based pharma sector. If it is true so for a developing economy – this must be answered separately for pioneering innovations and innovative improvements of known medicines.

The costs of conducting clinical and pre-clinical trials are so high that they constitute an insurmountable barrier for Polish pharma companies. The basic problem lies in the lack of initial capital and the long waiting time for return on investment, and the uncertainty as to whether investment will indeed yield returns. Economic barriers related to the introduction of a medicinal product on the market are not outweighed by the benefits of patent protection.

This conclusion might be problematized by the fact that several Polish companies have been struggling to develop new medicinal products, i.e. medicines based on new chemical entities. However, in most of the cases, these companies do not intend to bring their product to the phase of market authorization, but rather, they plan to sell the rights to the invention at an advanced phase of R&D. In such cases, patents are obviously necessary to recoup the investment, so one may assume that they do stimulate breakthrough innovations in this case.

The decisive question is whether the term "innovation" applies to products which have not been introduced on the market, but nevertheless have been commercialized. If we interpret the "implementation" criterion broadly, as covering the sale of product even if not yet ready for the market, then we may say that patents do indeed stimulate breakthrough innovations.

However, if we follow the ordinary meaning of "implementation", it can be concluded that patents are not strong enough incentives for innovations, which are understood as new medicinal products authorized for the market.

We can conclude that within the Polish pharma industry, patents – and more broadly industrial property rights – stimulate innovative R&D, but they do not incentivize pharmaceutical innovations. However, they do stimulate secondary innovations, mostly in the generic sector.

There are two specific groups of companies that are not interested in patent protection at all. Companies producing copies of medicines have no patentable material and therefore no interest in parents. By contrast, companies in the field of molecular protect their innovative technologies as trade secrets due to their short market lifespan.

In the medtech sector, patent protection is unavailable to one group of companies, namely those specializing in telemedicine.

Other industrial property rights used to protect innovative product or services include trademarks, utility

models and designs. Each right has a specific function within the entire body of legal protection for pharma and medtech products.

Trademarks build goodwill and prestige and create customer loyalty to certain goods. However, any link with innovation is very indirect and evident only insofar as they distinguish the quality and innovative character of goods.

Utility models and designs may support secondary innovations, especially in the medtech sector, by protecting products and technologies from imitation. Their significance as stimulators of innovations is much smaller than that of patents.

Since there are no innovative medicinal products being developed and marketed as reference drugs in Poland, SPCs and data exclusivity instruments have no significance for the pharma sector.

Barriers to innovation and potential for changes

Barriers to innovative activities and potential changes concern numerous problematic areas:

» Law

Within IP law the most important proposals concern: the rules of granting interim injunctions, premises of legal interest in invalidation of patents, the interpretation of the Bolar exception, and manufacturing waivers in the regulation of SPCs. Whereas manufacturing waiver is now subject to the pending novelization of the SPC regulation, the remaining proposals, long reported in the doctrine, were not taken into account in the currently proposed amendments to the Polish law on industrial property.

There is high demand for a specialized patent court. This idea has been proposed numerous times among IP scholars, policy makers and judges themselves, but it has never become the subject of a legislative proposal. Taking into account more and more complicated patent cases and the ongoing specialization of patent courts abroad, this proposal should be given significant attention by the current government.

» Financial support

EU funds are appreciated, but are seen as too focused on basic research instead of implementation and the commercialization of innovations for the market. This may be interpreted as a sign of growing maturity in the health sector in Poland. Both business and academia seem to be satisfied with the numerous grants for basic research; in order to advance innovation to the next stage, financial support for introducing new products and technologies to the market is needed.

» Education

Proposals concerning education are very diverse. They start with programs for primary and secondary school, requesting the implementation of a more practical, hands-on approach to learning in the sciences. Similarly, programs of studies, especially at scientific faculties, are seen as too theoretical. Other proposals relate to overall rules for research work in academia and the internationalization of research teams.

» Cooperation between sectors and technology transfer

This area probably attracted the most critical opinions. Centers of technology transfers and innovation brokers are seen as not working in the interest of the health sector. Cooperation with the public sector is seen as very difficult, due to the persistence of a mentality rooted in the former socioeconomic regime. The use of inventions at Polish universities is assessed as not likely to happen due to low levels of innovation in comparison with worldwide standards.

The numbers of barriers cited indicate that Poland is lacking a long-term governmental strategy with regard to innovation in the health sector, and needs to present a holistic approach, involving many institutions and agencies and creating a coherent legal ecosystem. Existing governmental documents, declarations and policies are often short-sighted and far too optimistic, especially in reference to the innovative pharma industry.

On the grounds of the conducted interviews and given responses, another conclusion may be drawn. Average knowledge about IP protection in the Polish health industry is still rather weak. While there is a group of companies that have highly specialized and skilled managers in this area, many of the representatives of this sector do not have elementary understanding of the role and rules of IP.

Apart from the suggestions of the interviewed companies, it would be also advisable for Polish poli-

cy makers to examine trends in innovation policies in the foreign health sectors. Some developments worth of analyzing are:

- negotiations on reimbursement of medicines led by a group of countries, intended to achieve lower drug prices; this mechanism could be successful only with block of countries characterized by similar population and prices of medicinal products.

- stimulating innovative activities in the health sector by introducing specific criteria for reimbursement pricing; here, the so-called "reimbursement mode for development", long-awaited in the Polish law on reimbursement, is highly relevant.

- reliefs within corporate tax, e.g. "patent box" tax instruments (as already under consideration in planned novelization of law on corporate tax).

- risk-sharing instruments in reimbursement policy, whic reimburse the price of a certain drug only if it results in the expected health benefits.

- stimulating clinical trials in Poland; Poland is first among emerging markets and 10th in the world in terms of the number of centers in which clinical trials are conducted; however, both the relative number of patients participating in the research and the number of centers in relation to the population are lower than in other EU countries.

As rightly pointed out in the review of this paper, any postulates of changes, as expressed by the interviewees, must be considered and assessed in the light of their compliance with the EU rules on fundamental freedoms, especially those concerning freedom of establishment as well as freedom of goods and services. This reservation applies in particular to the rules of drug reimbursement that are expected to be more favorable for the domestic industry. The amendments in the reimbursement scheme must however not have a discriminatory effect on the basis of origin of medicinal products.

Innovation in the Polish health sector in brief

Level of innovation in the health industry in Poland is very diversified.

In terms of breakthrough innovations, the medtech sector dominates, presenting solutions that are considered innovative on a global scale, such as an artificial heart, bone substitution materials, implants for traumatology, and artificial tissues. Other examples of innovations in this sector include devices for diagnosis in neurophysiology, devices for early diagnosis of breast cancer, and stents and biodegradable dressings for chronic wounds. Relatively, many Polish companies work on highly innovative telemedicine devices and IT solutions for medicine.

The majority of innovative activities in the pharma sector concern improved versions of known medicines. Several biotechnological companies offer products and technologies related to molecular biology, such as the isolation or amplification of nucleic acids. A few companies from this sector work on new chemical entities for oncological or immune-oncological treatment, and one elaborates nanoparticles for the delivery of oncological drugs. However, most of the breakthrough solutions remain in the phase of early stage innovation.

Such a landscape of innovation confirms a purely economic calculation: Poland has greater potential for medtech innovation than pharma innovation because genuine pharmaceutical innovation is prohibitively expensive for Polish companies right now.

Neither the patent system nor the IP system as a whole provide a strong enough incentive to undertake the extremely expensive and risky investment in R&D required for an original medicinal product. Another model of financing is needed to stimulate the innovative pharmaceutical industry.

Similarly to levels of innovation, the broadly understood culture of innovation in the health industry is very diversified, not only between the two sectors, but also among the companies within them.

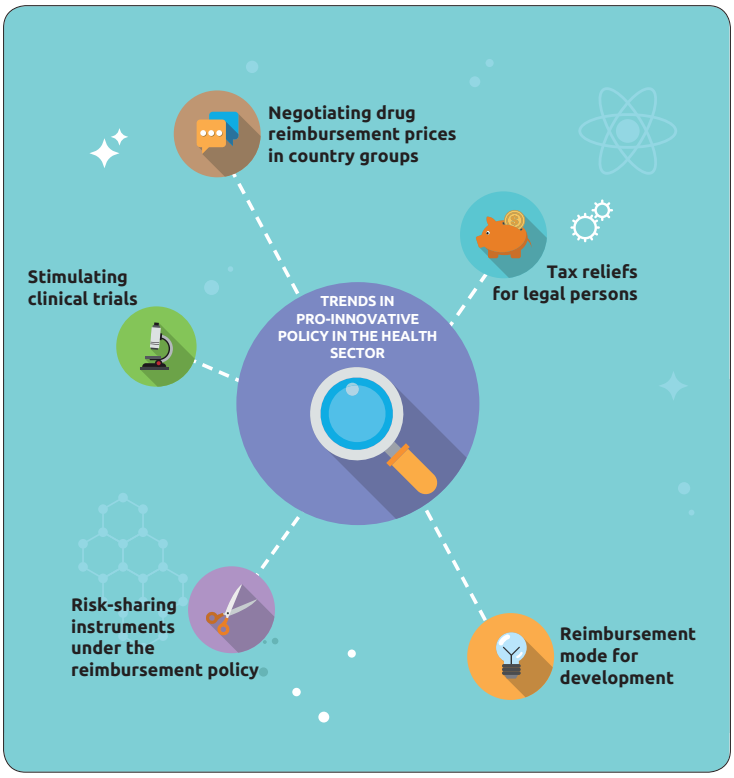
In the pharma sector, bigger generic companies are more accustomed to patent protection; they pay more attention to it and have the resources to achieve it, both at home and abroad.

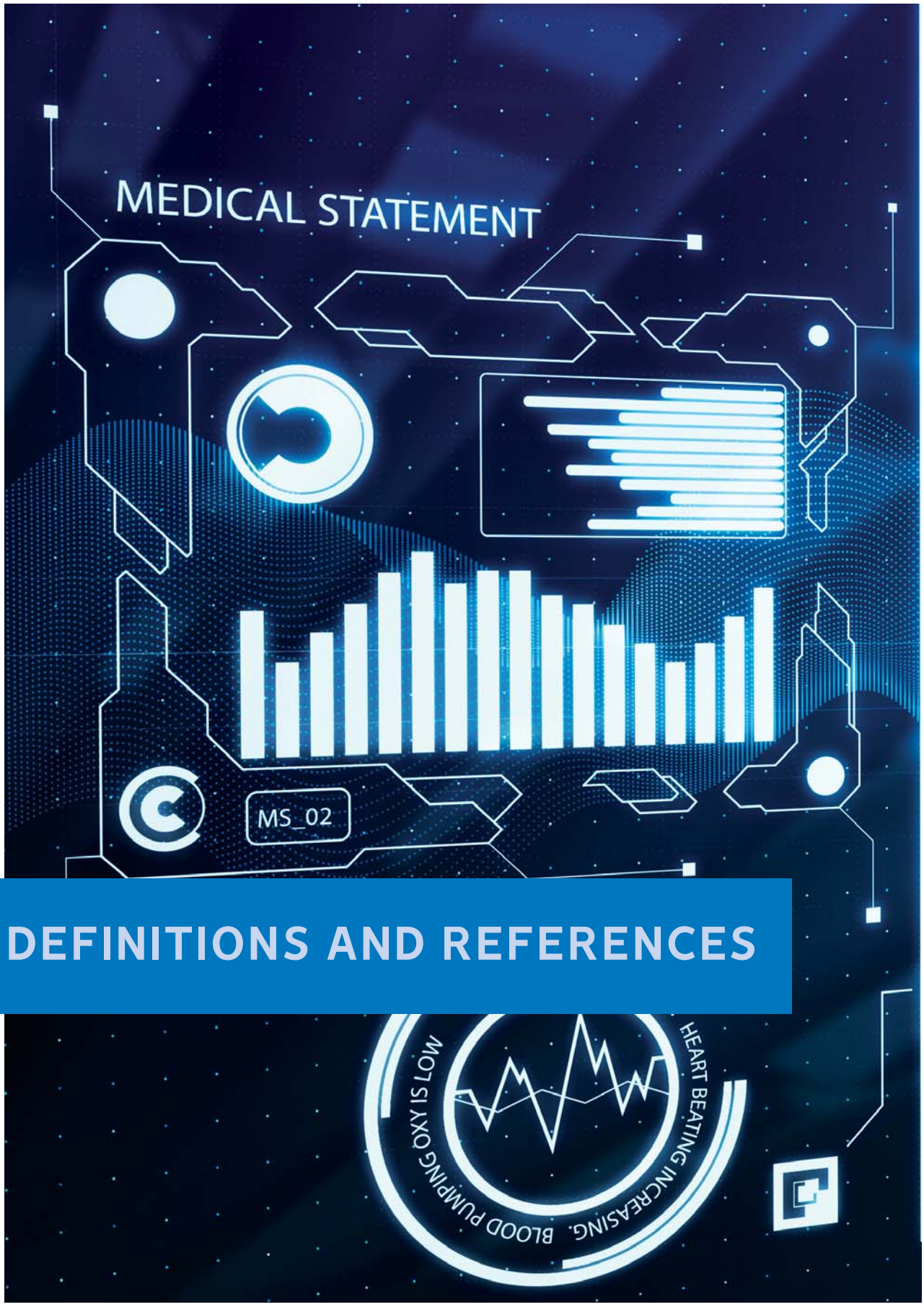
Patents are less important for smaller companies and more difficult to obtain due to high costs. They stimulate mostly secondary innovation in this sector. By contrast, usage of patent system is more problematic for medtech companies, but at the same time, the patent system stimulates both breakthrough and improvement innovation in this sector.

The pharma sector sees more direct benefit from patents, in terms of higher prices for medicines, sales of shares, or sales of patent rights. The medtech sector benefits from patents indirectly, in that patents enhance the company's prestige and reputation and build financial credibility.

The culture of innovation in both sectors is still relatively immature. Various forms of IP protection, patent strategies and dispute settlement strategies are still relatively young phenomena. Companies in both sectors use patent protection primarily as a defensive tool, which may mean that they do not perceive themselves as strong enough to compete on the global market.

When assessing innovation in the Polish health sector, it must be noted that Poland free-market economy is only 30 years old. The health sector innovations achieved in this short time prove that Poland has indisputable potential in this field. Let this analysis, including its proposals and comments, contribute to creation of an optimal legal, economic and social environment for developing this potential.





DEFINITIONS AND REFERENCES

Definitions

Innovation – the implementation of a new or significantly improved product (good or service) or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations. See: OECD, 2005, "The Measurement of Scientific and Technological Activities: Guidelines for Collecting and Interpreting Innovation Data: Oslo Manual, Third Edition" prepared by the Working Party of National Experts on Scientific and Technology Indicators, OECD, Paris, para. 146.

Breakthrough innovation – in the health sector, this is an innovation characterized by a completely new approach to prevention, treatment or diagnosis. In the pharmaceutical sector, breakthrough innovations are usually based on the development of a new chemical as the active ingredient of a medicinal product.

Refinement or improvement innovation, secondary innovation – in the health sector, this is usually a modified or improved version of a previously known product or method used in prophylaxis, treatment or diagnosis. In the pharmaceutical sector, improvement usually involves the development of a new dose of a known drug, a new pharmaceutical form or method of administration, or a new manufacturing technology of a known medicinal product.

Medicinal product – according to art. 1(2) of Directive 2001/83/EC, this is (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Reference medicinal products – a medicinal product authorized under Article 6, in accordance with provisions of Article 8(3) of Directive 2001/83/EC (OJ L 311, 28.11.2001, p. 67) and the corresponding art. 10(4) of the Polish Pharmaceutical Law (OJ 2001 No 126, 1381), i.e. a medicinal products authorized on the basis of complete pharmaceutical dossier, comprising especially results of preclinical tests and clinical trials.

Generic medicinal products – a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. According to art. 10(1) of Directive 2001/83/EC and art. 15(a) of the Polish Pharmaceutical Law, generic medicinal products are authorized in an abridged procedure, without submitting results of preclinical tests and clinical trials, but basing on the data of a reference.

Biological medicinal product – a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterization and the determination of its quality a combination of physic-chemical-biological testing, together with the production process and its control. See: Part I of Annex I of Directive 2001/83/EC, as amended by Directive 2003/63/EC.

Biosimilar medicinal product (biosimilar) – a product which is similar to a biological reference medicinal product. The active substance of a biosimilar medicine is a known biological active substance and similar to the one of the reference medicinal product. A similar biological medicinal product and its reference medicinal product are expected to have the same safety and efficacy profile and are generally used to treat the same conditions. See: EMA Procedural advice for users of the centralized procedure for similar biological medicinal products applications of 5 May 2017, EMA/940451/2011.

OTC product (over-the-counter medicine) – a product that can be purchased without a medical prescription, see art. 72 and 71 of Directive 2001/83/EC and art. 23a of the Polish Pharmaceutical Law.

SPC – supplementary protection certificate, a sui generis IP right granting an extension of patent for a medicinal product, provided by Regulation 469/2009 (OJ L 152, 16.6.2009, p. 1) and chapter 51 of the Polish Law on Industrial Property.

Freedom to operate examination – a search aimed at ensuring that certain commercial or professional activities regarding a technical solution do not infringe third parties' rights.

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ANNEX. SURVEY INTERVIEW SCRIPT

A. Introduction

1. How would you define your company's field of activity and its development directions?
2. What does the term "innovation" mean to you?
3. And what does the "innovation" mean in the health sector?
4. Is innovation an effective way of ensuring the market success of your company?
5. What is important to customers on your market and what affects their purchasing decisions?

B. Company's products

Let's talk about your company and the solutions it offers. Whenever I mention word "products" in the subsequent parts of the interview, I refer to the products, technologies, technical solutions, systems or services, which your company offers. Under the term "new product", I understand not only previously unknown products, but also the equivalents of known solutions, which your company introduces to the market (e.g. generic drugs or biosimilars).

6. For the purpose of this interview, could you shortly explain what products or types of products your company offers?
7. What is the significance of introducing products new to the market in your business?
8. Is your company concentrated on the Polish market or does it conduct or plan to conduct any export activity? If your company conducts export activity, does it offer the same products in Poland and abroad?
9. Were you inspired by ideas of other companies while developing your products? Could you give some examples, please? If yes, how did you gather information about those products?
    A. Was in such cases patent information of any use, for instance inventions disclosed in patent publications of other companies? Could you give some examples, please?
    B. If there had already been similar solutions on the market, what was the aim of developing your own equivalent product? In what ways would your equivalent be better?
    C. Have you ever tried licensing the rights to develop and market such solutions from other organizations?
10. Have the consumers (such as patients, doctors, healthcare facilities) ever suggested you any ideas for a product or its improvement? Could you give some examples, please?
11. Has your company conducted any analyses of consumers' needs with a view to developing or improving its products? If yes, how did these analyses look like and who conducted them? Were they formalized and resulted in development of any specific documents? Could you give some examples, please?
12. While developing or improving your products, do you concentrate on the needs of consumers in Poland or are your thinking of the global market right away?
13. Have any solutions from a completely different area or line of business inspired your company's solution? Could you give some examples, please?
14. Do your employees systematically monitor the development of scientific research in the area that refers to your business activity? If yes – what exactly does such a monitoring consist in?

15. Do your employees systematically monitor the development of solutions offered or submitted for patenting by your competitors? If yes – what does such a monitoring consist in?

C. Development of new solutions

16. How do you understand the term "research and development (R&D) activities"?

17. Is there a separate R&D department in your company? If yes, how many people work for this department? If not, does your company employ people in charge of developing or improving products?

    A. In what company department do they work?

    B. How many employees are there altogether?

18. What specifically does the work concerning developing new products or improving the existing ones consist in?

19. Knowledge from which specific areas of science and/or technology is indispensable for developing or improving your products?

20. Are works concerning developing new products or improving the existing ones formalized, that is:

    A. Are they based on a written plan?

    B. Are they conducted in order to achieve previously defined technical parameters?

    C. Are they based on a time schedule with assigned tasks and task performers?

    D. Do they have a set budget?

    E. Were they selected for carrying out on a basis of specific criteria?

    F. Are they subject to periodical performance reviews (how frequently)?

    G. Are people in managerial or project positions held accountable for the achieved R&D results or awarded additional bonuses or promotions in this respect (including also rewards for generating inventions)?

21. Where do the funds used to cover the costs of your developing or improving products come from?

22. How expensive is it to develop new products in your field of activity?

23. Have you conducted clinical research related to your products?

24. Are your works on developing and introducing new products to the market cheaper than those of other companies? Why so?

25. How long did a sample project of developing and introducing to the market your company's product take?

26. Do you think this project was shorter than in other companies?

27. Where do the differences in project timelines come from?

28. Have you conducted R&D activities aimed at improvement of products licensed from other entities? If yes, has conducting such works or subsequent use of their results by your company involved any problems?

29. Have you conducted also any research, which was not directly related to the development or improvement of products or product-related research involving patients, but served to enhance the knowledge in a given area?

30. How are your company's employees encouraged to experiment, generate new ideas and improve products?

31. Have employees in charge of developing or improving products left your company for your competitors? If yes, how does your company protect itself against disclosing confidential information by company employees?

D. Partnership collaboration

32. Has your company conducted contracted works on developing and improving products or contracted product-related research involving patients? If yes, have you subsequently used the results of such research in your activities?

33. Do you use solutions of other entities (not linked to you by shareholding structures) or individual inventors, as a result of distribution agreement, purchase or licensing of rights? Could you tell me more about your experiences in this respect?

34. Has your company ever conducted any works on developing or improving products jointly with other companies, e.g. in a formal consortium? If yes, has the pursuit of these works or the subsequent use of their results involved any problems?

35. Has your company ever commissioned to other entities or individual persons any works on developing or improving products or product-related research involving patients? If yes –could you provide some examples, please?

36. Does your company collaborate with universities or research institutes on developing/improving products or carrying out product-related research involving patients? If not, why? And what could encourage you to such collaboration?

    A. If yes, what universities or research institutes have you co-operated with?

        a. Was it a permanent or a short-term co-operation?

        b. would you please tell me more about this co-operation? Were your experiences positive?

        c. Have you had any problems while collaborating with universities or research institutes? Could you please tell me about such cases?

37. Have you applied for public funding of an R&D project jointly with universities or research institutes?

38. Does any of your company employees work in parallel also at any university or research institute? If yes, is their work in the science sector in any way beneficial to your business activity?

39. Does your company actively search for inventions created by employees of universities or research institutes?

40. How would you assess the possibilities of commercialization by your company of inventions created at universities or research institutes in Poland?

41. Has your company ever used the services provided by technology transfer offices, university SPVs (special purpose vehicles) or innovation brokers in the science sector? If yes, could you tell me more about your experiences, please?

42. Were you ever faced with any specific barriers for collaboration with the science sector?

43. How would you assess the level of knowledge and skills of the staff at Polish universities or research institutes in your field of activity?

44. What could contribute to closer cooperation between your company and universities or research institutes?

E. Patents

For the attention of the interviewer: some interviewees might mistake patent with an industrial design, utility model or a trademark, this question refers only to patents.

45. Does your company own any patents in force on the territory of Poland or has it filed any application for a patent in Poland? If your company does not own any patents or has not filed any patent applications, why is this so?

If a company does not own any patents/has not filed any patent applications, please skip the subsequent questions and go to the section F of the script starting with question no. 62.

46. Are these patents or patent applications related to: (a) new products (components, materials), (b) new applications of known products or (c) technological processes (including among others manufacturing methods)? By the term "product" I refer to compounds, substances, compositions and devices.

47. Did the inventions submitted for patent protection result from works planned by the company or were they created independently from such formal projects?

48. What made you file the patent application?

49. Have you encountered any problems with obtaining patents based on the patent applications filed?

50. Has filing a patent application and/or owning a patent brought your company any tangible benefits?

51. Are the inventions, for which patent applications have been filed, currently used by your company? If not, why?

    A. If yes, how many of them are used in-house, and how many were licensed out to other entities?

52. Has your company filed patent applications jointly with other entities, companies, scientific institutions or private persons? If yes, what were the challenges you faced?

53. Have you ever applied for patent protection for your inventions in other countries than Poland?

54. How important is patent protection to your business activity on the foreign markets?

55. How do you select the countries for patent protection of your products? Do these countries match the list of countries to which your company exports products? If not, why?

56. Have you ever intentionally resign from patent protection in a specific country due to protection costs or any other reasons?

57. Has your company ever took part in a litigation proceedings related to patent protection e.g. with regards to opposition filed by third parties?

58. Who in your company manages the intellectual property rights (including their registration, application and maintenance)?

59. Does your company cooperate with a patent attorneys practice? If yes, what apart from preparing a patent application is the patent attorney's support needed for?

60. Have you conducted or commissioned preliminary state-of-the-art search prior to making decision on preparing patent application?

61. Does your company have a formal procedure or criteria helping decide whether to maintain your IP rights in force, in particular: which patent to renew and which to abandon?

F. Benefits from Intellectual Property Protection

62. Does your company run any records (documents) with regards to intellectual property or intangible assets?

63. Does your company have any formalized policy and/or procedures related to intellectual property management?

64. Have your employees participated in any trainings (including: internal trainings) on intellectual property management?

65. In your opinion, what might be the benefits of patents?

66. Is there any risk in not protecting your intellectual property?

67. What intellectual property rights might be used to protect your company's products?

68. Do you know of any examples in your line of business in Poland where patents proved useful in the relations with investors or banks? This question refers also to the experiences of your company.

69. Do you know of any examples from your line of business in Poland where patents or patent applications proved useful in relations with government institutions? This question refers also to the experiences of your company.

70. Do you know of any examples from your line of business in Poland where patents or patent applications were of significance in corporate M&As (mergers and acquisitions)? This question refers also to the experiences of your company.

71. Do you know any examples from your line of business in Poland where the use of IP contributed to an increase in revenues and/or profits of a company? This question refers also to the experiences of your company.

72. Have you observed any situation where patents or patent applications proved useful in the procedures concerning product registrations, applying for marketing authorization, inscription on the lists of publicly reimbursed products or in the public procurement?

73. How does the use of patents affect the product prices in the health sector?

74. How does the use of patents affect the intensity of competition in the health sector?

75. Do you analyze patents or patent applications of other entities?

76. How do you know that your solutions do not infringe on others' patents?

77. Has anyone ever drawn your attention to the fact that your products infringe on someone else's patents?

    A. If yes, what happened at those times?

78. Does your company – apart from or instead of patenting – try to protect your solutions in any other way?

79. Does such an approach indeed prevent the competitors from copying? Or maybe it involves some risk factors?

80. In what additional ways does your company protect itself against the risk of competitors copying your company's solutions?

81. Are these protective measures effective?

82. Could your products be easily copied or counterfeited?

83. How can you defend yourselves against such infringements?

84. Has your company ever made available rights to use your solutions to other entities, e.g. by means of licensing agreements? If yes, could you tell me about such cases?

85. Do you use other forms of industrial property protection such as utility models, industrial designs or trademarks? If yes, what specific forms of industrial property protection are we talking about and what is their significance to your business activity?

G. Intellectual Property Protection System

86. How does the Polish system of intellectual property protection affect the innovativeness in the health sector?

87. How does it differ from the relations observed in other countries?

88. Have there been any cases of IP protection abuses by other companies that negatively impacted your business activities? Please discuss the examples.

89. Has your company experienced any other problems resulting from the abuse of IP protection by other entities?

90. Does your company have any negative experiences linked with the use of Supplementary Protection Certificates (SPCs) by other entities?

H. Public support

91. Which market segments in the health sector (which encompasses inter alia pharmacy, medical technologies and services) offer the biggest opportunities for development of Polish companies and should be supported by the Polish government?

92. How do Polish government institutions support domestic companies that develop new products for the market of health protection?

93. Is this support sufficient?

94. Do legal regulations and reimbursement systems create favorable conditions for the development, improvement and market introduction of new products by domestic companies?

95. Are there any important legal regulations lacking in your field of activity?

96. Do you think there is a need for any amendments of legal regulations affecting innovativeness and/or intellectual property protection in the health sector?

97. Do you know any priorities of the government (e.g. the Ministry of Health), which could affect your decisions on developing new products and/or protecting intellectual property in the health sector?

98. What incentives offered by public institutions stimulate your company's works on developing, improving and introducing products to the market?

99. What other incentives or solutions, which are in place abroad, could be useful but are currently not available in Poland?

100. What could be done better by the Polish government institutions to increase the innovativeness of the health sector?