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The Strategic Role of Medical Affairs Department in a Pharmaceutical Company

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Abstract: The pharmaceutical industry is a highly regulated and strategic sector of the national and global economies. Through the years it became one of the most important areas of governmental interest and control because of its impact on the state of society. The Medical Affairs Department in a pharmaceutical company is one of the areas that individuals with medical training or experience are most interested in working in. This department's extensive operational breadth impacts all aspects of how a pharmaceutical company is run, serving as a guardian over regulatory compliance, business strategy and pharmacovigilance for the available and ongoing medical issues. Understanding the subtleties of the relationships and linkages between Medical Affairs and any other area of such large corporations is not always easy. In this article, I investigated and discussed the strategic role of the Medical Affairs Department in a pharmaceutical company to explore how the competitive advantage for the company is being built with the use of this specific department.

Keywords: medical affairs, medical affairs department, pharmaceutical industry, pharmaceutical company, strategy

1. Introduction

The pharmaceutical industry is a highly regulated and strategic sector of the national and global economies. Through the years it became one of the most important areas of governmental interest and control because of its impact on the state of society. Social responsibility for the research, development, production and distribution of medications, if disturbed, can cause multidimensional damage on every level of the national economy (Runge and Runge, 2008).

The availability of drugs on the national markets remains in the care of national health institutions such as the Ministry of Health in Poland. The development of and investments in this industry positively result in increasing the availability of drugs, higher access to innovative therapies, development of new job places and improving the health state and wealth of the society (Eger and Mahlich, 2014).

Historically, due to the growing therapeutic demand and the rising problem of drug resistance, the search for new and effective types of medicinal substances and therapies has become the goal of many pharmaceutical researchers around the world (Gershell and Atkins, 2003). The development of science nowadays has contributed to the creation of new methods of isolation and chemical synthesis of compounds with a precisely defined structure and initially predicted properties. The result of this search is the regular introduction of new medicinal products to the pharmaceutical market (Cragg et al., 2014). The pharmaceutical industry's significance has surged in response to contemporary global challenges, exemplified by its pivotal role in addressing the COVID-19 pandemic through vaccine development and treatments. Additionally, the industry's importance has been underscored by its efforts to combat antibiotic resistance, ensuring robust healthcare solutions for emerging infectious diseases.

Taking into consideration the definition of the health and pharmaceutical industry as a systemic whole, pharmaceutical companies seem valuable, but also challenging, in terms of everyday duties and responsibilities, especially for people professionally educated and trained in this area (medical doctors, pharmacists, nurses, physiotherapists, etc.). The prospect of working in the pharmaceutical industry gives many development opportunities offering many career paths. The diversity of positions, roles and obligations allows for extending the knowledge and acquiring numerous professional skills. One of the desired departments in a pharmaceutical company, especially for people with medical education and/or background, is the Medical Affairs Department. The scope of operation of this department is complex and affects all aspects of the functioning of a pharmaceutical company, acting as a guardian of regulatory compliance, strategy and pharmacovigilance of the offered medical products. The understanding the nuances of connections and dependencies between Medical Affairs and any other part of such big companies is not always easy, not to mention the position of the Medical Affairs Department in the company as a whole organization.

This article aims to explore and describe the strategic role of Medical Affairs in pharmaceutical companies to understand how the competitive advantage for the company is being built with the use of this specific department. Therefore, I decided to approach this research topic, to better understand positions, roles and contributions of the Medical Affairs Department in a pharmaceutical company.

2. The Definition and Roles of the Medical Affairs Department

The main role of the pharmaceutical industry, as a supplier of medical products, is to perform uninterrupted research and development (R&D), manufacturing and sales of drugs, but also medical devices and food supplements to improve patients' health (Kitsis, 2011). Rapid progress in treatment possibilities has been made in recent years. The extension of lifespan, caused by effective therapies for diseases of the circulatory system, respiratory system or musculoskeletal system, has increased the incidence of diseases caused by abnormal cell division or abnormal gene expression (Meder, 2011). This important milestone unfortunately is not translated into a significant decline in patient mortality, especially when it comes to the field of cancerous diseases (Siegel et al., 2023). Clinicians, scientists, physicians and pharmacists have come a long way together from understanding many diseases and healthcare problems from the beginning of identification and description to knowing how to prevent, cure and/or control them.

In pharmaceutical companies, the entire responsibility of the complex medical area lies within the Medical Affairs Department (called also Medical Affairs, MA). Despite the rising importance and significance of this area, there is no one and only standard and best definition of the MA. It seems that it is extremely difficult to formulate one specific definition of Medical Affairs when there is a great diversity of organisations' examples and functions played by such a unit. Furthermore, it was also noticed that since the COVID-19 epidemic, the way that companies are operating has changed significantly. This applies also to the operations of Medical Affairs. That is why to keep constant patients' interests (such as the highest possible safety and efficacy of therapies provided) at the forefront of these rapid changes that in the past years had provided a ground for ethical violations, there should be common agreement established and efforts addressed to the creation of a standardized definition to guide policies align with practice due to the importance of the area (Jandhyala, 2022).

When it comes to building a common understanding of Medical Affairs, it is important to incorporate key functions, roles and responsibilities to find parts present in different organisations. The main role of Medical Affairs is to act as the company's point of contact with the outside world for all medical and scientific activities (Nell, 2018). Universal characteristics should encompass the fundamental ideas of Medical Affairs as a field of medicine that drives medical advancement and produces real-world data. It is important for particular stakeholders such as medical doctors (MD), healthcare professionals (HCPs), key opinion leaders (KOLs) and, last but not least, patients themselves, to secure and advance the interests of patients through practice and policy regulation.

In this sense, the Medical Affairs Department can be organised and established on 5 main principles:

- 1) it is the representation scientific body of a pharmaceutical company, as medical specialists and experts (and also a representation of the patient's needs),

- 2) it plays the educational role of using understandable messages and examples to provide up-to-date knowledge and secure the safety of medicinal products,
- 3) it plays the leadership role in the medicine development cycle (during both pre- and post-marketing stages),
- 4) it generates real-world evidence (RWE) and the specification of distinct stakeholders who cooperate with and benefit from Medical Affairs,
- 5) it is the compliance keeper acting as an auditor and controller in the organization within the rules of law (local/national, European and global regulations).

It is important to put all of these requirements into practice, not just theoretically, to implement the advanced and leading edge of the Medical Affairs Department creating pharmaceutical products and company strategy. End-to-end strategic planning must be at the same time practical and actual according to regulatory requirements, which is why it is frequently revised, checked and improved (Krendyukov and Nasy, 2022).

To invent, introduce and implement new drugs to the market three main stages of development are most important:

- Research and Development (R&D) stage, from ideation (even performed by computers) to the point when the product is chemically stable, synthesised or naturally obtained and thoroughly examined to check the mechanism of action (MOA), but also primarily assessed about the safety and efficacy of it;
- Clinical Trials (CT) stage, when the human safety and efficacy are further examined and the data is collected, extensively researched, and statistically assessed to understand how the drug affects the patient's health;
- Commercialization stage, when marketing authorization is applied and granted; after that selling of the products is legal and can be performed.

The modern Medical Affairs Department is organised as a separate and independent entity to distinguish medical and commercial (purely marketing) functions. At first sight, it seems like an additional and unnecessary cost to the company, but due to the increased regulatory burden, it allows it to concentrate on post-approval activities to present mostly medical, scientific and clinical expertise (Jain, 2017).

To see all roles and responsibilities of the Medical Affairs it is needed to understand the internal environment of the department, in the form such parts as the working groups or subdivisions and their distinguished obligations. Moreover, the external environment plays an important role as the employees of Medical Affairs must work closely and collaborate not only with themselves, within their department, but also with other departments in the company, including Research and Development (R&D), Commercial (CA) and Regulatory Affairs (RA) Departments to achieve common business goals of the entire company. It is important from the managerial perspective to create a common strategy for all of the departments and to align their strategies and ensure that the company's products are developed, marketed and used safely and effectively. The competitive impact of open

collaboration within and between the departments brings to the conclusion that it can help to save costs and increase revenues (Paul et al., 2010). The main goal of Medical Affairs is to support the operations of the company and ensure that all of the stakeholders, including healthcare professionals, have the necessary information they need to make informed decisions about the use of the company's products and that the products are used safely and effectively by doctors and patients. From the managerial perspective of the company, it is important to ensure communication at all levels and skilful change management as success factors in a highly dynamic environment (Jain, 2017).

Furthermore, it is also worth mentioning that different pharmaceutical companies might have different organisation and staffing levels in their Medical Affairs Departments and it is crucial to understand what are the processes and how many employees are needed to secure ongoing operations. Cross-functionality in the positions is preferable but specialisation is most commonly observed. Understaffing and/or unwanted/unpredicted rotation are highly disruptive for Medical Affairs. To find new, highly educated and experienced employees and to give them proper training and a level of understanding on an organisational level takes a lot of time and is a cost that can be preventable.

Medical Affairs Impact on Operations and Strategy of the Pharmaceutical Companies

Medical Affairs on the departmental level, but also on a personal level of each "medica" employee, should present patient centricity and promote activities leading to improvement of patients' situation, quality and comfort of patients' lives (Ashkenazy, 2020). A clearly defined medical governance mandate and leadership role of Medical Affairs affects many areas such as R&D, risk management, compliance, adverse events management, quality of processes, quality issues and complaints regarding products, education and training, promotional and educational materials, information and operational alignment (Dias, 2014). The assistance of Medical Affairs can be observed distinctly in a pharmaceutical company when its actions are compliant with company needs. Such a situation appears when Medical Affairs are allowed to focus on several key aspects:

- educational excellence, focus on science message,
- specialization in the covered area,
- product differentiation, competitive advantage seeking on the market,
- effective communication,
- creation of a system to understand employees' roles and responsibilities,
- clear separation of medical and commercial activities,
- establishing ongoing and strong relationships with key stakeholders,
- digitalization of the processes and effective exchange of knowledge between the company and HCPs.

From this perspective, patients' focus results in a direct and indirect influence on daily operations and strategy creation by the company in a couple of ways. First of all, there is a positive aspect that adjusts the company's operations and strategy to the needs of patients and to legal requirements that act as a regulatory catalyst. Secondly, Medical Affairs activities increase the competitive advantage of the company and increase the knowledge and awareness of employees. Last, but not least, there is an important aspect forced by Medical Affairs actions such as the emphasis on acting in accordance with procedures and focus on compliance.

3. Characteristics of the Pharmaceutical Industry

To fully perceive the role of Medical Affairs plays in a pharmaceutical company it is important to take a look at the environment that it is operating in, which is the pharmaceutical industry. It can be defined as a collection of all companies and organisations that work for a certain goal to invent, produce, sell or provide common and/or specific products which are in this case medicines (synonyms: pharmaceuticals, drugs, medicaments) and vaccines, but also medical devices and diagnostic tools. Some pharmaceutical companies produce additionally food supplements and cosmetics, but in most cases, it is not their primary focus area (Summers, 2007).

In economics, the idea of industry is crucial since it aids in understanding the composition, conduct and outcomes of various economic activities. A part of the pharmaceutical industry is the pharmaceutical market. Although they are closely connected, the pharmaceutical industry and the market are not the same things (Lakdawalla, 2018).

The markets of the pharmaceutical industry are typically distinguished by geographic borders (per countries where the company operates – sometimes one market covers a couple of countries by similarities) and/or by medical area (per therapeutic interest of the company – companies generally are specialized and are not willing to compete as this require great investments and may involve significant losses of revenues). Some markets are better than others for pharmaceutical companies. The Polish pharmaceutical market is considered promising, well-developed and still rising, as it gives a good location, easy access for highly experienced and well-educated specialists, who are moderately paid compared to other (especially Western) European countries and the US (Willert, 2007). That is why there are a lot of investments and production of drugs in Poland and pharmaceutical companies are willing to place their headquarters (HQ) and shared-service centres in our country (Kubiak, 2005).

The pharmaceutical industry is a strategic sector and governmental area of interest because of the high importance of social responsibility for the research, development, production, and distribution of medications. The development of and investments in this industry positively result in, e.g., increasing the avail-

ability of drugs, higher access to innovative therapies, developing new job places and improving the wealth of the society. Because of such great priority, the pharmaceutical industry is progressively growing, even despite disruptive world events (which even might be encouraging and, in some sense, be positive for the industry – such as the COVID-19 pandemic).

The Size and Growth of the Pharmaceutical Industry

Revenues, market capitalization and personnel count are only a few methods to describe the scale of an industry. In the last 20 years, the pharmaceutical industry was growing every year. The value of the worldwide pharmaceutical market as of the year 2020 was around 1.27 trillion dollars. Compared to 2001, when the market's worth was only 390 billion dollars, this represents a significant increase. In 2022 the growing trend was maintained and the whole global pharmaceutical market was valued at 1.48 trillion dollars. This is a slower increase from the 2021 valuation of 1.42 trillion dollars (Mikulic, 2023).

The worldwide pharmaceutical manufacturing industry, according to the analysis provided by Grand View Research, was expected to increase at a CAGR (Compound Annual Growth Rate) by 11.34% from 2021 to 2028 (Grand View Research, 2020). The progressive ageing of the population, rising occurrence of chronic and systemic illnesses, resistance to existing therapies and the rising need for modern and novel medications and treatments may be some of the causes contributing to this increase.

The pharmaceutical industry seems to be extremely attractive for millions of people worldwide working in this field. That includes scientists, researchers, engineers and other professionals cooperating. It is hard and nearly impossible to assess how many people work in total in the pharmaceutical industry. Data published in 2022 showed an estimation that in 2017 around 5.5 million people worldwide were employed directly by the pharmaceutical sector and the tendency is uninterruptedly growing (Mikulic, 2022).

To sum up, the pharmaceutical business is a crucial and quickly expanding sector that is fundamental to people's health and well-being on a worldwide scale. The implication of the industry development is direct: the more developed the industry, the more it will influence the health state of the societies positively, delivering more efficient drugs and therapies.

4. Research Design

This article aims to explore and describe the strategic role of the Medical Affairs Department in pharmaceutical companies. That was done with the use of a created scenario that served as the main tool for gathering data within this research. The

interview scenario was asked and answered by Medical Affairs employees and representatives from different companies, positions and overall years of work experience. The main goal is aligned with the ultimate objective of advancing knowledge of the Strategic Management field, which is why the research was focused on operations within the interesting area of the pharmaceutical industry. Overall, the research is of high importance because it sheds light on current trends, tendencies, future opportunities and directions in which Medical Affairs plays an important and leading role in day-to-day operations and can be translated to successful planning and creation of the strategy of every pharmaceutical company. The key aim of the research is focused on determining the state of knowledge within two main personal research interests: what is the strategic role of the Medical Affairs Department in a pharmaceutical company and what is the strategy for building a competitive advantage for the company with the use of MA. The research is intended to contribute to existing knowledge on strategy creation and support in strategic management within the pharmaceutical industry and to generate insights that can become future research interests and practical applications in the observed field. To answer this complex problem, it was necessary to identify research gaps and formulate research problems.

The gaps identified during the literature review process offered the chance to fill up the current knowledge state and add latest information to the topic. Then the respecting research questions were created, by defining precise subjects to be studied to reduce the research gaps and gather insights from the informants.

The identified research aspects were as follows.

- RQ1. What is the general role of Medical Affairs and how has the role of MA changed through the years?
- RQ2. How do Medical Affairs affect strategy?
- RQ3. How do Medical Affairs affect operations?

To answer these questions the scenario interview was created and performed among Medical Affairs employees from different global pharmaceutical companies, working on various positions and career levels. The interviews were conducted in person or in the form of an online interview with the use of audio-video technology (direct interview). In Table 1 the list of informants, their positions, years of experience and areas of specialization are presented.

Table 1. Description of research participants

Informant no.	Current position	Position experience (years)	Industry experience(years)	Supervised thematic/disease areas
1	2	3	4	5
1	medical director	1	14	hospital products (MS/oncology/ ophthalmology), RX Generics (pain, antithrombotic), OTC (cough & cold, pain, dermatology)

1	2	3	4	5
2	manager, clinical development	1.5	6	oncology, dermatology, gastroenterology
3	clinical project lead	1	9.5	dermatology (atopic dermatitis, pruritus) and diabetology (type i diabetes)
4	medical advisor	2.5	6	a therapeutic area not specified
5	medical science liaison (senior)	1.5	7	cancer screening for colorectal cancer, liver cancer and multi-cancer early detection (dedicated to 15 different types of cancer)
6	medical science liaison (junior)	0.5	7	cardiovascular, renal, metabolic diseases

Source: own work.

5. Research Findings

In the dynamic landscape of the pharmaceutical industry, the role of Medical Affairs has evolved significantly over the years, from a supportive function to a strategic business partner that influences various aspects of company operations. This executive summary presents insights gathered from interviews with industry professionals to explore the general role of Medical Affairs, its changing dynamics, and its influence on corporate strategy and operations.

Research Question I: What is the general role of Medical Affairs and how has the role of MA changed through the years?

The important role of Medical Affairs in a Pharmaceutical Company was observed, valued and noticed on every level of corporate structure by all of the informants. The shortest, but very insightful definition of Medical Affairs was provided by informant 1: *MA is a strategic business partner that plays a critical role in cooperation with medical society, which supports medicines introduction to medical society.* This shows the informant's clear vision and understanding of Medical Affairs' purpose. It was mentioned also, that MA is important in every step of drug introduction to the market, through pre- and post-marketing support activities. Moreover, was referred as well for patient direct and indirect support.

Informant 2 also accurately noticed that MA plays a critical and diverse role that can differ depending on the structure of the MA department across different companies: *Sometimes the different scope of activities of the company may result in different MA organization.*

From a Medical Advisor perspective, the role of an MA might seem more technical and is related to the decisive and informative support of the Marketing Department (advisory in the creation of marketing strategy, insights for marketing material development, marketing materials approval), Field Force (training) and Market Access Department (legal support). This approach is understandable from the role perspective, as this position consists of advising and supportive activities, which are very technical, specific and scientifically oriented. What was underlined by both Informants 5 and 6, conversations and discussions between Medical Affairs and external partners should be based on non-branded (purely scientific) materials. This is also related to ongoing discussions about partiality and medical compliance.

Current topics that are under discussion and control of MA are viewed similarly in every position, with this difference, that with every level higher in an organizational chart, the scope of activities is perceived as broader. Informant 2 said: *The MA department encompasses [...] a very broad scope of responsibilities. The MA team is responsible for executing important, more technical tasks such as adverse events (AE) reporting, literature monitoring, label creation and regulatory submissions. However, they also have a crucial role in educating employees and healthcare professionals about therapeutic areas and company products, providing medical information, developing relationships with HCPs and gaining an external perspective to incorporate into the company's strategy.* This description and point of view were reflected also in other participants' answers.

The primary responsibility of MA employees is to establish and develop professional relationships with both active and potential collaborators, not only to expand existing partnership opportunities but also to ensure that both discussion parties grow knowledge and enjoy an exceptional experience while cooperating. To achieve this, MA employees must maintain a high level of therapeutic and technical expertise, which enables them to engage in scientific discussions with HCPs and ensure that MA-limited resources are allocated correctly. Moreover, MA is expected to ensure timely information delivery and identify potential opportunities to accelerate product-on-market delivery, ultimately contributing to the successful execution of clinical trials or distribution. It was stated, by all of the participants, that the perspective of understanding MA role, was quite different both 5 and 10 years ago. It was evolving with time and the understanding was developed with experience. *I wasn't fully aware of the complexity of the role of MA and the multitude of tasks it entails* (Informant 2), *Now MA plays even more critical role especially once new first-in-class medicines are introduced to the medical society* (Informant 1), *Now there is more focus on clinical practice change and healthcare systemic solutions* (Informant 4), *I was not aware of an MSL role 10 years ago, and I saw myself more in clinical trials or pharmacovigilance rather than in core Medical Affairs unit* (Informant 6). Even during medical and pharmaceutical studies, the awareness of the MA role was not fully explained and some participants even criticized this fact. Overall, it seems right from the beginning of medical education to show the Medical Affairs Department, as the available path

of professional career to be chosen when deciding to work in a pharmaceutical company. When it comes to future trends that might play a significant role within the pharmaceutical industry, specifically when it comes to the MA role, Informant 1 answered: *Nothing special*. This can be interpreted dually. Medical Affairs leaders are either forward-thinking or too focused on present issues. The other respondents predict that numerous technical responsibilities of MA will be automated, such as AE reporting, while others will be fully digitized, for example, educational materials. Informant 2 added: *Nevertheless, even in the era of automation, I firmly believe that nothing can replace the direct relationships that MA has with healthcare professionals. These connections will remain critical in the future*. Informant 4 said that MA should focus on the development of omnichannel communication with HCPs which may be a result of the increased role of digital communication in MA's daily obligations. Informant 5 added, *From the provider's perspective role of the Medical Affairs will probably expand in the future since those providers are burned out to collaborate with sales representatives*. Representatives of the Medical Affairs Department usually have a higher level of education, which translates into greater credibility and trust in the medical community. It seems that MA will focus even more on building relationships with leaders of medical opinion. The exchange of ideas between specialists, units and their mutual support can play a significant role in the future.

Goal achieving can be understood differently, but all of the participants mentioned introduced by their companies KPI's (Key Performance Indicators). It is important that everybody in the company follows the same rules (i.e. one compliance) and understand common corporate goals (i.e. patients' needs at the centre of focus). From a Director's perspective, it was stated, that it is important to create and give employees goals and obligations to be understood and easily measured such as the number of visited KOLs, number of Advisory Boards organised or participated, number of MSL visits, number of medical information responses provided. It was mentioned that the goals should be SMART.

While each department within our MA team may have slightly different objectives, a shared goal we all strive towards is to generate scientific evidence that accurately demonstrates the value of our company's drugs. said Informant 2. That represents care for the company's needs and is aligned with the patient's needs.

Informant 5 mentioned also that the educational enrichment of patients, through HCPs education, can be considered an ultimate goal. The increase in medical knowledge can be beneficial and result in better therapy outcomes (with the use of better compliance and adherence). *Achieving the goal can be considered also, as an improving the understanding of the product by the customer as a result of scientific/educational exchange*. Informant 6 said: *The general goal is to deliver a proper drug to the right patient, but it is hard to measure. Also, the knowledge about an intervention, its safety profile, safety measures to be taken, benefit of it can be measured via sending surveys to KOLs*. So, the company's internal KPIs may be assessed by external stakeholders.

To identify areas for improvement, it is important to regularly assess the effectiveness of existing practices and processes. By conducting a thorough analysis, potential opportunities for optimization can be identified and addressed. *For instance, MA activities and education can have a significant impact on HCPs feeling more comfortable with using our drugs, which in turn can increase sales. However, the challenge lies in how to effectively measure such an effect.* (Informant 2) or 3rd party companies may also conduct a general survey on current knowledge of a whole or a part of the medical industry. Improvements in tracking can definitely be introduced (Informant 6). It was underlined that goals to be achieved should be personalized somehow, as employees in MA work in different fields facing certain barriers and challenges. It was indicated that there is still room for improvement in this area.

The question about MA, as a fully external service delivered for the company, resulted in finding a few potential and possible advantages of such a solution such as: economic, faster adaptation, new possibilities, flexibility of the service. On the other hand, there were a lot of doubts about such a solution: communication issues, lack of engagement, problems with knowledge transfer and delivery, know-how protection. After all, in all cases, the discussion resulted in the reflection that MA should not be fully outsourced, even if this solution is possible and can be introduced. It was mentioned that some tasks within MA can be outsourced, like the process of literature monitoring. However, collaboration with HCPs relies on having a direct connection and relationship with the representatives of pharmaceutical companies. It was mentioned that personal relation leads to a better overall customer experience and is beneficial for the company's overall results.

Research Question II: How do Medical Affairs affect strategy?

The informant's answers were summarized and organised into the following 5 internal stakeholder groups that Medical Affairs typically interacts with: Sales team, Market Access, Regulatory Affairs, Medical Advisors and MSAs, other internal stakeholders such as Clinical Trials Teams, Medical Information, Pharmacovigilance, Quality & Legal and IT teams.

MA needs to maintain strong relationships and effective communication with these stakeholder groups to ensure successful product development, launch, and ongoing support.

The informant's answers were summarized and organised into the following 5 external stakeholder groups that Medical Affairs typically interacts with: Key Opinion Leaders (KOLs), Healthcare Professionals (HCPs), Pharmacists, Regulatory Authority, other external stakeholders such as journalists, Contract Research Organisations (CROs), medical societies, patient organisations and healthcare organisations related to the therapeutic field. To efficiently develop, launch, and support pharmaceutical products on the market, as well as to uphold credibility and confidence within the medical profession and the general public, MA must engage with these external stakeholders. For ongoing collaboration Medical Affairs

employees interact with internal (inside the company) and external stakeholders (on the market) via a full range of communication methods: face-to-face meetings – mostly through MSL's visits, *via* phone, e-mail and virtual meetings. The only difference noticed in the way of communicating is that internal communication is more indirect/unofficial, and external is more direct and in a form of official communication.

Informant 2 gave an example of communication flow which can represent a complex cross-functional environment that an MA must establish to be fully operative: *As part of my job, I regularly communicate with investigative sites and CRO personnel to ensure the smooth and efficient delivery of clinical trials at the local level. We collaborate closely with regulatory authorities to ensure that all stages of our clinical trials align with their expectations and recommendations.* This kind of collaboration and communication flow must be established and maintained. It can be treated as a key asset of a company and can be considered as a value itself. From the interviews, it turned out that Medical Affairs contributed to the development of the business's strategy of the company. *MA is a very critical contributor which is responsible for the provision of interaction with KOLs that helps to accommodate drug prescribing* (Informant 1). *Although marketing and sales may play a larger role in a strategy for a compound that is already marketed and reimbursed, it is crucial to consider all the activities that were necessary beforehand* (Informant 2). MA representatives are the key contributors to research and development strategy, clinical development strategy, registration strategy, scientific data dissemination strategy and many others. Even for products that are already on the market, MA representatives are important contributors to brand plans, product launches and promotional activities. It was stated that MA employees possess the most knowledge to effectively emphasize the advantages of a drug and its efficacy. *MA acts by providing insights (gathered through interactions with physicians) and generating evidence (RWE, observational studies)* (Informant 4). All informants emphasized the fact, that MA feedback is always welcome and strongly considered in strategy planning locally and globally. In most of the cases (5 out of 6) there were individual Medical Strategies recognised, declared that it was officially presented in the form of official documents and aligned with overall company strategy (realizations of the same goals). Local-level strategies usually follow global concepts. It was noticed by Informant 2 that: *The MA department has an official medical strategy with some specific goals. In addition to this, there are also internal concepts within each department introduced. The goals set for MA are based on and aligned with the company's global goals.* Medical Affairs in most cases has its strategy tailored to its unique needs and responsibilities, but it is aligned with the main strategy presented by the company's business leadership. This is because some parts of the MA strategy are internal, due to medical compliance requirements. Despite this, MA remains a strategic business partner and an integral part of the company-wide strategy.

Research Question III: How do Medical Affairs affect operations?

Medical Affairs, which is in charge of imparting medical and scientific knowledge to a variety of stakeholders, including HCPs, regulatory authorities and patients, is essential to the functioning of a pharmaceutical company. The role is reflected in ensuring that a company's goods are reliable, efficient and used responsibly. In that way, MA may contribute to the company's success. Additionally, MA can support clinical trials and post-marketing surveillance, while also helping to develop new products. It was underlined by Informant 1 that: *Medical Affairs was always considered as a strategic business partner for all stakeholders, both internal and external.* MA has a significant impact on various aspects of company operations. This includes providing input into research and development, ensuring regulatory compliance and patient safety, supporting medical education, disseminating data and aiding in marketing efforts. MA helps to take the right business decisions by providing expertise knowledge and realization of projects aligned with the overall company strategy. Overall, the performance and reputation of a pharmaceutical company can be significantly impacted by MA's efficacy.

To perform well within Medical Affairs daily and achieve established long-term goals, a certain skill set is desired and helps to find ourselves in this environment. To stay up to date with the therapeutic area it is important to have a broader understanding of the market and products. Seeing the bigger picture from a broader than position-level perspective can be learned and is achieved with career progression. This requires knowledge of treatment paradigms, an understanding of what is important to clinicians and familiarity with the competitive landscape.

It was noticed and underlined by the majority of informants that formal education is required and beneficial, but soft skills and personality can play a key role in success while applying for a job in MA, especially when it comes to global pharmaceutical companies. The important hard skills for working in Medical Affairs include an understanding of medical terminology, medical or pharmaceutical education, advanced language skills (foremost full professional fluency in English), data analysis and a deep understanding of statistics. The important soft skills for working in Medical Affairs, according to informants, include good relationship building and a proactive approach to details in terms of medical aspects. Additionally, project management skills, science storytelling, strategy planning and presentation skills are also necessary. Other skills that were mentioned as essential, include the ability to operate under stress in a constantly changing environment and skilful change management.

It was underlined by all of the informants that effective communication and interpersonal skills are crucial. Negotiation skills are also important, as they allow for effectively advocating for the MA's perspective. Informants suggest that working in Medical Affairs requires a combination of soft skills, medical knowledge, communication abilities, project management and data analysis skills, as well as the ability to build long-lasting relationships and operate under pressure.

6. Conclusions and Recommendations

All of the informants were able to see the crucial value of the Medical Affairs Department in the Pharmaceutical Company they are currently working in and recognise the critical position that Medical Affairs plays at every level of the company hierarchy. It is important that everybody in the company follows the same rules (i.e. one for all compliance) and understand common corporate goals (i.e. patients' needs at the centre of focus). The forgotten and not fully realized role of Medical Universities is to develop the understanding of MA roles and responsibilities in the initial stages of future employee formation (even on the university level). Such a person will faster adapt to the reality of working in a global pharmaceutical company and corporate environment. Even during medical and pharmaceutical studies, the awareness of the MA role is nowadays not fully explained. The main duty of MA employees is to build relationships with both current and potential partners to increase partnership opportunities while also ensuring that both discussion partners gain knowledge and have open communication while working together. To achieve this goal, MA staff members must maintain an elevated level of therapeutic and technical proficiency, enabling them to engage in scientific conversations with HCPs and guarantee that MA's limited resources are deployed properly. Medical Affairs roles and responsibilities should not be fully outsourced, even if this solution is possible and can be introduced on a broader company scale. Some responsibilities can be automated or outsourced, yet the benefits of internal MA seem greater than the costs of the operations. According to the results of the interviews, the Medical Affairs Departments strongly influence the design of overall company strategy and operations. The introduced internal MA strategies are aligned with corporate ones. MA representatives are key contributors to research and development strategy, clinical development strategy, registration strategy, scientific data dissemination strategy and many other types of localized or inter-company/interdepartmental strategies. From the operations perspective, MA is providing input into research and development, ensuring regulatory compliance and patient safety, supporting medical education, disseminating data and aiding in marketing efforts. The departments act dually as an organiser and controllers (auditors of every aspect of the company's operations). MA helps to take the right business decisions by providing expertise knowledge and realization of projects aligned with the overall company strategy. It was underlined that MA feedback is always welcomed and strongly considered in strategy planning locally and globally. There is a high importance of strategy building with the connection of personal development of the employees on every career level within the industry, which is why companies spend monetary resources on employees' training and development paths. Formal education is required and beneficial, but soft skills and personality can play a leading role in success while applying for a job in MA, especially when it comes to global pharmaceutical companies. There is urgency observed in developing

communication at all levels and skilful change management, as a success factor in a highly dynamic environment. Overall, the performance and reputation of a pharmaceutical company can be significantly impacted by MA's efficacy.

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Strategiczna rola działu medycznego w firmie farmaceutycznej

Streszczenie: Przemysł farmaceutyczny jest wysoce regulowanym i strategicznym sektorem gospodarek krajowych i światowej. Przez lata stał się jednym z najważniejszych obszarów zainteresowania i kontroli rządów ze względu na swój wpływ na społeczeństwo. Pracą w dziale medycznym w firmach farmaceutycznych najbardziej zainteresowane są osoby z wykształceniem lub doświadczeniem medycznym. Duży zakres działania tego działu ma wpływ na wszystkie aspekty funkcjonowania firmy farmaceutycznej, ponieważ pełni funkcję strażnika zgodności z przepisami, strategii biznesowej i nadzoruje bezpieczeństwo farmakoterapii. Zrozumienie subtelnych powiązań między aktywnościami działu medycznego a innymi działami tak dużych korporacji nie zawsze jest łatwe. W niniejszej pracy badano i omówiono strategiczną rolę działu medycznego w firmie farmaceutycznej, aby opisać, w jaki sposób buduje się przewagę konkurencyjną firmy z wykorzystaniem tego konkretnego działu.

Słowa kluczowe: dział medyczny, przemysł farmaceutyczny, firma farmaceutyczna, strategia