

TECHNOLOGICAL FUTURE OF PHARMACEUTICAL INDUSTRY– DEVELOPMENT PERSPECTIVES

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Abstract

Digital revolution and innovations are the modern phenomena pharmaceutical industry should take advantage of. The prevention of diseases will also facilitate the progress of the sector. This publication examines the key factors influencing pharmaceutical industry behavior and bears the potential to drastically change the sector in the upcoming years. The forthcoming challenges and changes appearing on the horizon require careful and precise consideration of new kinds of markets, alternative business models or even a complete change in the way pharmaceutical companies operate. The future of the industry is defined by the introduction of various technologies that are currently changing and will continue to change all aspects of the industry – production of pharmaceuticals, supply chain, clinical trials, etc. The leading tendencies in the advancement of the pharmaceutical sector in 2019-2021 are also analyzed with a focus on new technologies and digitalization. Different trends have changed the sector inevitably having both short-term and long-term impact.

Keywords: *pharmaceutical industry; transformation; digital future; perspectives; artificial intelligence; drug development process; robotics*

JEL Codes: *I15; O14*

1. Introduction

The global pharmaceutical industry continued to invest efforts and dedicating resources in its development, despite the inevitable COVID-19-related transformation and the challenges it had to overcome in the last two years. Despite the global slowdown, the ambition to demonstrate innovative potential to launch new products and improve patients' lives in the rapidly evolving worldwide remains unchanged.

The leading role of technologies required a transition to innovative solutions such as artificial intelligence and software learning so as to ensure better processing and use of big data in the sector.

The major long-term developing tendency in the pharmaceutical sector in the last decade defined the shift from the production of traditional drugs with small molecules to biotechnologically centered strategies.

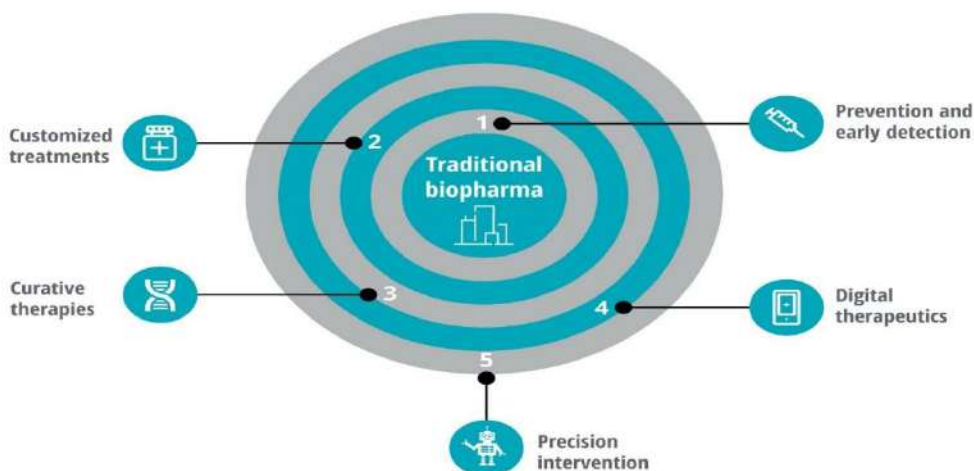
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The growing investments in research and advanced activities for the production of new pharmaceuticals, biological products, cell and gene therapy, etc. require solid expertise, experience and reliable infrastructure in the entire process of launching new pharmaceuticals, from their clinical creation to legitimate approval for market release.

Experienced and reputable experts, equipped with innovative development and production laboratories, will be permanently assigned the creation of drugs by pharmaceutical companies in the future. The industry will invest significantly in an organic and non-organic portfolio, including the production of small molecules and biological products, development of drugs, production of viral vectors, cell and gene therapy.

Nowadays, the development of pharmaceutical companies has been influenced by a number of factors, factors that can seriously remodel the sector in the upcoming years - Figure 1 (Yang et. al, 2020).

Figure 1. Five forces of potential disruption to the biopharma industry



Source: Deloitte Insights

Prevention and early diagnosis of illnesses, personalized treatment, innovative medical therapies, digital therapy and a precise use of sophisticated treatment technologies and medical products require careful attention. These factors can have significant impact on pharma companies and their patients (Yang et. al, 2020).

Establishing the future of healthcare, pharmaceutical companies need to consider new strategic investments to ensure success. Analysis of new markets, alternative business models or a total change in the operating methods will be highly

recommended for the drug sector to deal with the forthcoming changes appearing on the horizon.

2. Impact on pharmaceutical industry

Factor 1: Prediction and early detection

Prevention of disease and a shift to wellness is a core pillar of Deloitte's perspective on the future of health. We expect that over the next 20 years, we will be able to detect some diseases and prevent them from advancing possibly even before symptoms arise. Today, for example, clinicians can detect the early stages of melanoma much earlier than in the past, and early treatment can eliminate the disease completely (Yang et. al, 2020).

Factor 2: Personalized treatment

People suffer from diseases and respond to treatments in various ways. The vast majority of patients may not receive the full potential benefit of drugs that they are treated with, because we don't yet know how to effectively stratify patient populations. A therapy that is effective for one patient, might be different for another patient and never reach the optimal active concentration. Giving each patient a personalized dosage or the optimal combination of drugs, could lead to better outcomes.

Factor 3: Treatment therapies

The therapies can potentially reduce the frequency and spread of many diseases. Therapies of this kind are typically temporary and tend to reduce the symptoms of a disease by targeting the main condition in a permanent or semipermanent way. It is predicted that the single-genetic mutation can trigger diseases that will be among the first ones treated by this kind of therapy (for example different types of cancer, sickle cell anemia, and some rare diseases). More than 1000 clinical trials for cell and gene therapies were performed worldwide at the end of 2019. A variety of diseases (such as cancer, musculoskeletal disorders and neurodegenerative diseases for example) became the focus of these trials.

Factor 4: Digital therapy

Patients are equipped with software programmes that help prevent, manage or cure medical disorder or disease based on collected data. Technologies of this kind are a potential viable alternative to traditional pharmacologic treatments or can be used together with drugs, devices or other therapies, optimizing patients' caretaking and improving health results.

Factor 5: Precision intervention

The more sophisticated medical technology allows for earlier interventions and raises the effectiveness of procedures that reduce or even eliminate the need for pharmaceutical products. The advances in robotic surgery, nanotechnologies and tissue engineering are also included. Improvement of this technology can lead to

substantial progress in cancer treatment, treatment of infectious diseases, chronic pain and inflammatory conditions.

All of the above-mentioned factors raise serious questions for pharmaceutical companies about the markets they operate in and how the threat of disruption could impact them. The contemporary model of drugs sale treating symptoms or mitigating the progression of chronic diseases is no longer viable. The volume of sales of medicine in all variations of a disease could possibly be reduced due to more effective prevention, higher stratification of diseases, better tailoring of treatment regimens, an increase in curative therapies, behavioral intervention and advanced medical procedures. Considering the challenges arising, biopharma companies should ask themselves the following questions: How could each of these five factors affect their current business model? Where to find new opportunities? What are the potential threats for their current business? How can they unfold with time? How willing are they to participate in the emerging areas? How can they address the emerging challenges? How to react without regret (potential partnerships for example)? (Yang et. al, 2020).

Some diseases will be prevented, cured or controlled with non-pharmacological interventions by 2040. If this suggestion turns out to be true, less people will suffer from chronic diseases and less therapies will be needed. As a result, what has traditionally been managed by pharma sector, treatment of chronic diseases for example, is likely to erode. Consequently, if pharmaceutical companies wish to survive, a drastic change and significant expansion are essential. Furthermore, only pharma companies, who are able to transform their business models, could enjoy future success based on prevention, early detection and personalized therapies.

Pharmaceutical industry key tendency in development is the opportunity to use artificial intelligence algorithms that will ensure timely creation of innovative drugs and their successful launch, algorithms that facilitate the decision-making process of licensing, business strategy, merging and acquisition.

The variety of technologies introduced in pharma companies together with modalities represent another key trend in the pharmaceutical business development that will be further observed. Cell and gene therapies (CGT) will probably continue to be under the focus in the forthcoming years.

Pharma companies are now aware that the introduction of patient-oriented solutions depends on solid clinical evidence. Additionally, in terms of the highly regulated healthcare system, it becomes extremely hard to compete. Some novelties in the use of digital technologies in pharma industry are worth to be mentioned – the focus on the digital product effectiveness to generate solid evidence and the merge of generic drug manufacturers with technologically innovative companies in order to achieve higher productivity. Healthcare systems worldwide become more and more flexible and experiment with the current workflows, especially when aiming to improve effectiveness. Owing to a training and educational software for radiologists,

radiology can be given as a good example of improved working methods. IT products bear the potential to facilitate the functioning of a number of clinics in future.

The future of pharmaceutical industry will be continually marked by consolidation of development and manufacturing companies (CDMO) – a type of companies that provide both development and production of drugs. Companies offering a wide range of services with diverse customers' groups prove to be more viable.

The pharma industry now faces the challenge to create various drug delivery devices providing a personalized dose of medicine. The aim of achieving higher efficiency has led to more and more efforts being invested in the development of nasal forms of drugs. Companies have been recently working on the creation of electronic conceptual devices that will notify patients with a special application. These devices monitor the timely intake of medicines and inform the patient of the achieved dose effectiveness.

A few tendencies marked the development of pharma industry in 2020:

- increased use of marijuana for medical purposes;
- development (although slow-paced) of “precision medicine” that guarantees production of drugs in doses and intake forms tailored to patients' needs;
- integration of block chain technology;
- digital solutions installation;
- reduction of industrial capacity;
- use of cloud technologies;
- periodical pricing and strict continuous control on price speculation;
- digital training of professionals and a greater focus on R&D to ensure quality clinical trials, and tests that will allow to identify drugs and to improve business expertise and patients' lives.

3. Pharmaceutical industry trends in 2021

The main problems of 2021 were closely related to the pandemic and its outcomes. The leading industrial problems and trends of 2021 are connected with cybersecurity development, antimicrobial resistance, environment, supply chain challenges, shift from animal testing, digital transformation and digital clinical trials (Sokolova, 2021).

The continuous digital transformation of pharma industry allows big data collection and management online, but at the same time creates a risk of cyberattacks. Some of the problems the pharma industry has to handle are intellectual property theft, cyber espionage, cyberattacks, such as Ramson ware and Phishing attacks. Moreover, serious risks concerning COVID-19 vaccine emerge – cyber espionage to steal vaccine data, cyberattacks on online platforms for vaccine appointments and use of stolen data to misinform the population.

The excessive and uncontrollable use of antibiotics has not only led to antimicrobial resistance, but appears to be one of the greatest challenges for pharma industry that affects healthcare systems worldwide and in particular pharmaceuticals. WHO defines antimicrobial resistance as one of the ten great global health threats in 2019 just before the pandemic outbreak, that can be explained with the unlimited access to antimicrobial drugs, inappropriate prescription and the restricted knowledge patients have (WHO, 2019). The appearance of COVID-19 pandemic worsened the situation.

The development of new antibiotics is extremely necessary, but antimicrobial resistance develops much faster than their respective research and experiments. In addition, according to WHO analysis almost all new antibiotics entering the pharma market in the last decades are simply variations of drugs, developed before the 80s of 20th century and cannot be as effective as expected (WHO, 2021). Consequently, these new drugs are incapable to handle the challenge of antimicrobial resistance spread. Pharma industry has the important task to develop innovative drugs providing sustainable funding for research.

A substantial negative impact on surrounding living organisms is caused by pharma manufacturer's waste, with chemicals being disposed in water and soil. Furthermore, pharmaceutical waste is also generated by chemists and hospitals and a certain number of medicines traditionally used by households are disposed as garbage.

A few more factors contributing to the environmental pollution by the industry appeared with the coronavirus pandemic: the number of plastic personal protective equipment (PPE; gloves, surgical and non-surgical masks, gowns, face shields, etc.) produced and used worldwide has significantly risen. In addition to the previous efforts to reduce negative ecological impact, driven by the COVID-19 pandemic, the pharma industry is forced to take additional measures to combat environmental pollution.

The continuing COVID-19 crisis has resulted in disrupted pharmaceutical supply chains. Just like in any other industry, pharma industry faces the problems of reduced workforce due to illnesses or even deaths, travel restrictions, technological hardships, change in specific drugs demands and great insecurity. The key challenges pharma supply chains have to deal with are the scarcity of raw materials and vaccine distribution.

The shortage of raw materials and active pharma ingredients (API) is caused by the great impact of coronavirus pandemic on their two world leading producers – China and India. In February 2020, the Food and Drug Administration (FDA) in the USA announced the first case of drug shortage in China after the coronavirus outbreak (U.S. FDA, 2020). The situation has not improved much since then. Indian pharmaceutical industry is highly dependent on the raw materials imported from China with 70% of Chinese API being exported to India. Export restriction of more than 20 APIs in March 2021 was imposed by the Ministry of Trade and Industry of

India due to the rising number of COVID-19 cases. Moreover, the last mass pandemic in India triggered a drastic price rise of raw materials with up to 200% (Chandna, 2021). All these factors globally impacted all pharma industries around the world, since they can lead to a shortage of basic drugs used for active treatment of acute conditions or chronic diseases.

The latest vaccination campaign proved to be not only the biggest and fastest in human history, but it also faced a number of challenges. Some of the challenges was associated with the distribution logistics, because the vaccine is highly dependent on the cold delivery specific requirements (for example, use of dry ice or refrigerators storage during transportation, Bluetooth to monitor and control temperatures, etc.). Reaching the final destination brought additional challenges such as ensuring security (video recording of vaccines storage area, application of GPS sensors to define location during transportation, etc.) and the most suitable storage device (refrigerator, freezer, ultra-freezer with low temperature, etc.). Countries with low and medium living standards and income found it extremely hard to meet these requirements, because most of them do not have proper infrastructure for effective storage, transportation and delivery of vaccines.

The traditional biomedical testing on animals is typical for the pharma industry. Despite the fact that the latest statistical data proves that 92% of animal-tested medicines are ineffective for humans, only 0,02% of animal-tested medicines are available to the public (Hanson, 2021). In spite of the idea that the shift from animal testing is a process that requires a lot of time, a few alternative testing methods are already in use: in vitro testing, computer modelling, participation of volunteers, and human-patient simulation. In general, the pharmaceutical industry has now been paving the way for standards that exclude animal testing.

One of the major trends in the development of pharmaceutical industry in 2021 is the industrial digitalization that started just before the COVID-19 outbreak. Some technology achievements allow for increased production and better quality of drugs thus improving the competitiveness of pharma companies – the artificial intelligence. Concerning the artificial intelligence, COVID-19 pandemics turned out to be a necessary evil that accelerated the introduction of technologies in the pharmaceutical industry: according to the IT company Global Data report artificial intelligence is likely to transform the pharmaceutical industry in the forthcoming years (Global Data report, 2021). The urgent need for vaccines and drugs for COVID-19 prevention and treatment has triggered innovations and represent a turning point for the introduction of such technology in the industry.

The contribution of artificial intelligence for the acceleration of the drug development process was also outlined in some online articles of “The Guardian” (Kollewe, 2021). Pharma companies have been always criticized for the slow technological progress. Special attention must be paid to the fact that the process of drug development is a slow, expensive and relatively successful process without

artificial intelligence: research and testing, acquiring legitimate approval of every new drug require approximately a decade and more than \$ 2 billion investment. Artificial intelligence contributes to the reduction of time needed for big scientific data analysis in order to better understand the specifics of a certain disease and to find potential candidates for treatment. The technological ability to compare thousands of data pages published online within seconds is the greatest advantage. What is more, artificial intelligence allowed for a quick and successful COVID-19 vaccine development. In addition to elaboration of drugs, innovations can be applied in a wide range of other activities that will allow for better design and recruitment of participants for clinical trials, more intelligent and effective supply chains, targeted sales and marketing.

According to a recent report on the use of robotics in industry, the need of automation in pharmaceutical production units is growing (Market Analysis Report, 2021). The solution to the problem can be found in the introduction of robotics to pharma manufacturing. Coronavirus pandemic additionally accelerated this process as pharmaceutical companies had to overcome the workforce shortage and increase domestic production through automation, rather than outsourcing. The report also demonstrated the various benefits of using robotics in drug manufacturing: improved productivity and quality of drugs, space utilization, less workforce turnover, increased safety, reduced downtime, better waste management. As for the production itself, automation reduces the error rate and frees people from monotonous and time-consuming work, raising the productivity of a plant. In the USA, for example, the partnership between Clemson College of Engineering, Computing and Applied Sciences (Clemson College) and the company Nephron Pharmaceuticals led to the invention of a syringe filling robot (Clemson University, 2021). The process of filling syringes with drugs is traditionally carried out by technicians and requires up to five professionals daily. The robot can fill, close and seal syringes without any human intervention.

Using robotics has proved to be effective, the tendency will continue after the COVID-19 crisis as well: the long-term benefits of robots make them a cost-effective tool in the production process. The digital clinical trials suggest limited or no personal interaction between the patients and the researchers. Connected devices, telemedicine and mobile providers of healthcare services allow distant data collection. All activities from A to Z can be distantly implemented in patients' homes. Among other benefits, clinical trials of this type provide patients with a more streamlined experience, reduce the time-consuming personal visits and better access to patients in rural areas or remote communities. However, there are certain risks such as unknown side effects or wrongful use of data.

COVID-19 catalysed the adoption of decentralized clinical trials and they immediately turned into strategic priorities for many pharmaceutical organizations. This trend is expected to last long after the coronavirus crisis since these trials bear the potential to change fundamentally the clinical trial procedure.

4. Conclusion

Having both short-term and long-term impact on all of the above-mentioned tendencies in the development of pharma industry in the last two years, will undoubtedly change it. It is worth mentioning that a growth of \$1.5 trillion in pharma sector in 2023 is forecasted. It is also expected that pharma industry will be significantly affected by innovative technological breakthroughs in the next two to five years. More than 450 drugs were withdrawn from the pharma market in the last 25 years. That is one of the reasons why precision medicine will be an inseparable part of the pharma industry transformation. Considering the perspectives on the technological future of the pharmaceutical industry presented in this article, we can conclude that the sector is ready for the adoption of Industry 4.0. The pharmaceutical model is definitely transitioning to digital solutions, key research innovations and new emerging markets. The role of artificial intelligence, robotics and research and development (R&D) of pharmaceuticals, is evident. Probably, mobile health applications will even transform healthcare and diagnostics. Big data and digitalization processes will also impact the manufacturing and distribution of pharmaceuticals. The exact changes are yet to be seen.

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