

EVOLUTION IN PHARMACEUTICAL INDUSTRY

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Abstract: The purpose of this research was to evaluate the significance and influence of emerging technology in the pharmaceutical sector. The study also looks at strategic ambitions for the growth of technical needs, the acknowledgment of IT inventions that assist patient care services, and the readiness of pharmacists to adopt inventions. The assumptions were thus to analyze the influence of new technology on the pharmaceutical sector, whether favorable or negative. Primary and secondary datasets were collected using two types of respondents. As a result, 100 people were chosen for the questionnaire and 15 for the interview-based data collection. Pharmacy students, teachers/researchers, and pharmaceutical company personnel were all included. According to the survey, new technologies have had a favorable impact on the expansion of the pharmaceutical industry. The pharmaceutical sector will benefit more from new technology in the future when it comes to growing its operations in the fields it has chosen, it has been concluded. However, it is also found that some respondents are dissatisfied with certain of the technologies employed. The report suggests that pharmacists set up training sessions to introduce staff to new technologies. It also argues that artificial intelligence should be used in the pharmaceutical industry, which may not result in a reduction in employment because there will be a significant drop in AI errors.

Keywords: Artificial intelligence; barcode medicine identification; internet; electronic medical record; mobile technology; Telecare technology; electronic prescription and discharge system; pharmaceutical industry; new technologies; pharmacists; technology.

INTRODUCTION

The way we live has changed dramatically in recent decades as a result of technology's influence on every aspect of human life, including communication, transportation, manufacturing, business, and the pharmaceutical and medical industries [1,2]. As a result, it is clear that pharmacists in the present day are utilizing IT systems to design and construct their daily tasks in a more efficient and productive manner [3,4]. The technological system has a low degree of complexity and mistake in the working process, is simple to use, and allows for the management of more work in less time [5]. Research and development and production are heavily reliant on the technology-based system, thus the IT needs for cutting-edge operational procedures are also seen as important features of the pharmaceutical industry [6,7,8]. The emergence of new technology considers the fact that reliable and steady accuracy, consistency and unwavering use of terms and taxonomy, and mass customization, which is the ability of Information Technology (IT) to make its services available to a vast community worldwide, thus far, in a manner that can be personalized to the entity [9,10,11], make day-to-day life more efficient, monotonous and repetitive. In besides allowing the storage of patient planned proceedings and records, new technologies (such as artificial intelligence, barcode medicine identification, the internet, electronic medical records, mobile technology, telecare technology, electronic prescription and discharge system, etc.) can also facilitate the creation of the electronic statute of limitations, administration, and management., a Automate the movement and handle of pharmaceuticals along the value chain and equip yourself with the tools necessary to keep an eye on the cost and security of currently being used pharmaceuticals [12,13]. As a result, IT can advance patient security and safety, enable professionals and specialists in the pharmaceutical sector to provide high-class and good treatment, and help patients understand the majority of their medications [14,15,16]. IT has significantly and most adversely affected life worldwide over the past few years [17,18]. Due to the numerous benefits of automated IT, many production companies have a grip with digital technology [19,13]. Due to changing disease eugenics, growing population burden, and restrictive healthcare requirements, people have faced enormous obstacles on a global scale. In the past, pharmacists had to confront a wide range of challenges related to their profession [20,21]. These multiple challenges are all overcome by increasing the role and involvement of new technologies as part of the global drive for universal healthcare. To meet these issues, it is essential to recognize how important technology is [22,23].

Historical Background

For more than three thousand years, people have used "drugs" to treat diseases and illnesses. Around 1100 BCE, a small number of pharmaceuticals of both plant and animal origins were recorded in China, and by the end of the 16th century, at least 1900 different medicines were in use there. [24] More than 13,000 medicines are now approved by traditional Chinese medicine. The five volumes of De Material Medica, the earliest pharmacopoeia outside of China, were composed in the first century CE by the Greek botanist Dioscorides. [25] Many indigenous tribes around the world, including those in North and South America [26] India [27] Australia [28] and Africa, have herbal practitioners from this early era identified in them. Both the Islamic⁸ and Christian [29] sections of the late mediaeval era saw a rebirth in herbalism. This practice persisted into the 17th century and included the works of Culpepper [31] in England and Paracelsus [30] in Switzerland. One of the earliest pharmacopoeias in the English language was Culpepper's The English Physician, which was published in 1652. [32]

Empiricism had been the sole basis for herbal medicine use up until the 18th century; practitioners knew what worked but did not understand why or how it did so. However, the fundamentals of pharmacology—the study of pharmacological activities and also how they produce their impacts to take shape in the 18th century.

One of the first individuals to investigate and isolate the active component in a herbal cure was William Withering^[33] in the 1780s. He separated digitalis from the foxglove and described how to remove it from different plant sections, what happens next, and the best approach to provide it to patients. Over the course of the following century, pharmacology slowly advanced, and Oswald Schmiedeberg (1838–1921) is today widely regarded as the discipline's creator.^[34] He was appointed head of pharmacology at the University of Strasburg in Austria in 1872. There, he researched the pharmacology of chloroform and chloral hydrate before publishing the venerable text *Outline of Pharmacology* in 1878. Coincidentally, modern organic chemistry also began to emerge at around the same time as pharmacology. Before the 19th century, chemists had generally believed that compounds obtained from living organisms were endowed with a “vital force” By coincidence, the development of contemporary organic chemistry began about the same time as pharmacology. The prevailing consensus among chemists prior to the 19th century was that chemicals derived from living organisms were endowed with a "vital force" that set them apart from inorganic molecules. But in 1828, Friedrich Wohler converted the purely inorganic substance ammonium cyanate into the organic molecule urea, which is a component of urine. Even though Wohler was always wary of asserting that he had refuted the doctrine of vital force, this incident is frequently seen as the birth of organic chemistry.^[35] The pharmaceutical industry was established in the final decade of the 19th century as a result of these two scientific breakthroughs in pharmacology and organic chemistry, among other advancements.

The modern pharmaceutical industry has two main antecedents: first, newly established dyestuff and chemical companies like Bayer, ICI, Pfizer & Sandoz established research labs and discovered medical applications for their products. Second, companies like Merck, Eli Lilly and Roche that had previously supplied natural products like morphine, quinine, and strychnine moved into large-scale drug production in the middle of the 19th century. However, development was only moderate, and the majority of medications were still available over the counter in the beginning of the 1930s. Nearly half of them were locally manufactured by pharmacists, and in many cases, doctors themselves gave out medications to their patients. However, the early 20th century saw a number of significant developments. Hippocrates noted that the natural component of willow bark known as salicylic acid had analgesic qualities. Aspirin was developed in 1897 by Bayer chemists who showed that a chemically altered form of salicylic acid had much increased efficacy.^[36] Penicillin and insulin were discovered and produced in the 1920s and 1930s, albeit on a small scale. The Second World War significantly boosted the industry's growth by necessitating the large-scale production of analgesics and antibiotics as well as increased pressure from governments to do research to find cures for a variety of ailments. In the years following the war, state State-run healthcare systems, like the UK's National Health Service (NHS)^[37], were implemented across Europe, creating a far more stable market for prescriptions of medicines and, more significantly, their payment. This resulted in a significant incentive for additional commercial research, development, and manufacturing investment. Along with the expansion of the government's role, the production of medicines has been subject to more government regulation on both sides of the Atlantic. With the introduction of new analgesics like acetaminophen and ibuprofen as well as entirely new classes of pharmaceuticals like oral contraceptives, β -blockers, ACE inhibitors, benzodiazepines, and a variety of novel anti-cancer medications, the post-war period from the 1950s to the 1990s saw significant advances in drug development.

The thalidomide scandal of 1961^[38] prompted a thorough review of government oversight of the sector. The need for proof of efficacy, purity, and safety was now mandated by new rules, which greatly increased the time and money needed for research and development, notably for the clinical testing of new medications.^[39] There was a significant amount of industry consolidation as entry hurdles to the drug manufacture business were increased. Globalization processes, which had started before the war, also accelerated. As a result, a small number of very large multinational corporations began to dominate the development of new drugs, ushering in the age of the "blockbuster" medicine The ulcer drug Tagamet, which was invented in 1977, was the first ever pharmaceutical to achieve commercial success, earning its makers, GSK, more than US\$ 1 billion annually and its inventors the Nobel Prize. Then came a series of items, each of which seemed to be more successful than the one before it. Eli Lilly developed Prozac, the first selective serotonin reuptake inhibitor (SSRI), in 1987, and Astra unveiled omeprazole, the first proton pump inhibitor (PPI), in 1989. With sales of more than US\$ 125 billion over roughly 15 years, atorvastatin, launched as Lipitor in 1996, became the most successful medication ever. The business was undoubtedly at its peak at this time, with research producing a seemingly endless stream of increasingly popular and lucrative goods. However, since that time, the sector has been plagued by a number of significant issues, many of which have yet to be resolved.

Civilization in Pharmaceutical Industries

AstraZeneca, GlaxoSmithKline (GSK), Eli Lilly, Merck, Novartis, Roche, and Pfizer are a few of the very large multinational businesses that make up the pharmaceutical industry in the eyes of the majority of people. These businesses are collectively referred to as "Big Pharma," a derogatory term.^[40] This, however, is incredibly false. Even though Teva is the 11th-largest pharmaceutical company in the world^[41] and may very well be the source of the medication that they are now taking, it is quite likely that the general public has never heard of either of them if you ask them if they have heard of Teva or Mylan.

In some ways, the pharmaceutical industry is similar to an iceberg. In terms of finance, these well-known companies, which are broadly categorized as research-based pharmaceutical companies, account for about 40% of the market^[41]; however, they make up a relatively small portion of the industry as a whole, with more than 90% of pharmaceutical firms, also known as generic firms, being largely unknown to the general public. In turn, the great majority of medications sold are produced by these generic drug

companies. Generic drugs filled 84% of the 4 billion prescriptions written in the USA ^[42] in 2013. The patent system is to blame for this unequal scenario because big research pharmaceutical corporations spend many billions of dollars looking for new medicines. ^[43,44] The majority of candidate medications never reach the market because they are discovered to be ineffective during development or to have severe adverse effects that prevent their usage in patients. A tiny number of novel medications do, however, reach the market each year, and the patent system makes sure that, for a short while, the inventive business has the sole right to market the novel drug. Anyone may produce and market what is now known as a "generic pharmaceutical" when the patent expires. Almost all medications, or all those that are out of patent, which are produced and marketed by generic pharmaceutical firms. Pharmaceutical research businesses rarely have a successful product, whereas generic pharmaceutical companies never do. The profile of the company, how businesses are set up, and how they run are all significantly impacted by this.

Companies that produce generic medications are low-cost, low-margin, and low-risk enterprises. The goods they decide to produce and promote have previously proven to be worthwhile and profitable in the marketplace. Generic businesses are not required to spend money on research and development, although some of the larger businesses do so in order to bring more cost-effective and efficient manufacturing. Although there are strict regulations for manufacturing in this sector, there are few products and relatively modest manufacturing costs. Since the products are already well known in the market and the demand is clear, marketing expenses are also extremely minimal. In many ways, generic pharmaceutical firms compete in commodities marketplaces where price and profitability are the primary sources of competitive distinction.

The business models used by the research pharmaceutical businesses are totally different. These forward-thinking businesses introduce the latest drugs to the market. This is exceedingly costly, time-consuming, and fraught with great risk. The pharmaceutical industry spends a lot of money on research and development, but the majority of the expenditures are incurred during development activities, particularly during the clinical trials that come after pre-clinical development.

When studying illness and disease, it is occasionally possible to pinpoint specific chemical targets that could benefit from treatment. Then, it is possible to employ high-throughput screening and other techniques to find potential chemicals that could make good drug candidates. After that, research is transitioned into development for the most likely candidate(s). This comprises assessing the prospective drug's effectiveness, which is one of the key concerns, as well as the possibility of any serious negative effects (safety). Additionally, it's important to look into whether the active ingredient can be converted into a usable medicine and administered to the patient in a satisfactory manner. The success rate during this period of development is incredibly low: only 1% of potential pharmaceuticals ultimately reach the pharmacy. As regulatory requirements grow and people, both inside and outside the industry, grow more risk adverse, this rate is only becoming worse.

Research, Discovery and Development

Since practically any substance has the potential to be used as a medicine, as we saw in Section 1.2, how do we choose which ones to use? When apothecaries and herbalists were still in use, knowledge was based solely on empirical evidence, and substances were only employed once they had been proven to be effective. Until written records were made available, this important knowledge was passed down orally. Although we have much more knowledge now than the herbalists did in the first century, the process of discovering new drugs is, at least in theory, fairly similar. It is appropriate to note the most current statement made by a medicinal chemist:^[45]

"Medical chemistry is still primarily an observational field of study. (Given how little math any of us has to know, that ought to have been evident.) We have broad hypotheses, patterns, and rules of thumb, but none of them are very helpful, and our data consistently astounds us. If you have the correct personality type, that could be fun, but it's definitely not relaxing, and most of the time it's not particularly profitable either.

An outline of the procedure for creating a novel pharmaceutical is given in the section that follows. Given the poor success rate, research pharmaceutical companies' R&D divisions will not only be looking at one medicine at a time but also at numerous other compounds at various stages of the development cycle. A major company's development pipeline may have 100–200 compounds active at any given moment.^[46]

Problem Statement

Regarding patient care and safety, pharmacists are faced with numerous challenges. However, the pharmaceutical business has deployed new technology consistently and successfully over time to address these issues. However, it is necessary to acknowledge the significance of the emerging technology in the pharmaceutical sector. As a result, the latest study makes an attempt to comprehend the requirement for new technologies, both now and in the future.

LITERATURE REVIEW

The study's hypotheses are as follows:

Innovative technology use aids the pharmaceutical industry.

The pharmaceutical industry's use of new technologies conclusion has a negative impact on the target field.

The study by Meier et al ^[47] encourages pharmacy schools to design a curriculum that can adapt to pharmacists' changing roles and responsibilities, as well as to use new technologies as much as possible so that students can initially fully comprehend the significance of new technologies as well as how to use potential inventions to improve patient care services. Furthermore, they argue that pharmacy students must be equipped with the information and skills needed to do the current, technologically enhanced profession of a pharmacist in the twenty-first century.

David and Bruno ^[48] investigated how pharmacists are involved in and have learnt about the use of current technologies, particularly their role in hospital emergency rooms, in their study.

They also focused on the potential cost savings associated with the use of new technology and the utilization strategy developed by the pharmacists in their study. According to the survey, pharmacists have gained and portray the supporting role of health care professionals by providing pharmaceutical knowledge, dose recommendations, and regulatory guidance, among other things. Jaiswal et al. ^[49] emphasize the importance of emerging technology in the pharmaceutical business in advancing the field's advancement in their study. Physicians and pharmacists may be able to facilitate and make possible the storage of patient records by obtaining new technology, as well as accelerate the development of the electronic decree of restriction. automation of the conduct and treatment of medications in the value chain, as well as the provision of equipment to monitor the effectiveness and safety of medicines in use. In their study, Jacobs, Caballero, Parmar, and Kane ^[50] looked at how doctors and employees directly communicate instructions to pharmacists using electronic means. Additionally, they understood the need of emerging technologies in helping to collect and maintain patient records and data so that patients can receive accurate and crucial consulting services. They looked into how to order medications using new technologies under the competent and current supervision of technological advancements.

METHODOLOGIES

The methodology of a study is crucial since it outlines the procedures the researcher employed to carry out the study. Readers can determine whether the sources of information used in the research were gathered from trustworthy sources or not using the research methodology as a justification tool. The research technique is utilized in this study to tell the readers about the procedures used in order to carry out the research. The research design, data collection techniques, and sampling procedures have all been covered in this section. To efficiently obtain research results, a variety of research methodologies are accessible. Both quantitative and qualitative research methodologies are available. A third research approach is a mixed approach, which combines the two approaches ^[51,52,53]. The mix method research methodology is employed in this study to efficiently examine the findings.

Data Collection

Survey and interview participants are employed in this study to gather both primary and secondary data ^[54,55,56]. Both research approaches are used to perform this study in order to collect more information that yields better results. The invitation was extended to potential participants as part of the primary data collection using the educational platform of the Faculty of Pharmacy, Benazir Bhutto Shaheed University, Lyari, Karachi. 100 undergraduate Pharm-D students who were enrolled in various courses and programmed for the spring 2019 semester as a result were chosen. The study's goals were explained to the survey respondents, and they received instructions on how to complete the survey. For the second batch of data, the pharmacy professionals involved both at the teaching/research and practicing/ development levels in the field of pharmacy and pharmaceuticals were asked to supply their input. Together with e-mail invites, Facebook & WhatsApp messages welcomed a total of 110 well-known university teachers and internationally renowned professionals whose prestige was derived either from their publications or their professional achievements. In response to our invitations, a total of 15 experts pledged to take part, 4 university teachers and 16 employees of the pharmaceutical companies.

RESULTS

The findings are extremely significant because they were obtained using the primary research method, in which a questionnaire was filled out by 100 respondents, who provided important information regarding the subject under discussion. In order to gather further information, a total of 15 interviews with professors, researchers, and workers of pharmaceutical businesses were also undertaken. The survey results acquired using the questionnaire instrument are first presented in this section, followed by the interview results and a discussion of the findings.

The Pharmaceutical Industry in The Future

Commercial pressure

As several problems appear at once, the research pharmaceutical sector of the industry is currently experiencing a serious crisis. Since the introduction of the first blockbuster drug, cimetidine, by GSK in the 1970s, both the industry and regulators have been persuaded that the "blockbuster model" for the industry represents the long-term path forward: drug discovery and development was known to be costly, time-consuming, and high risk, and that after patent expiration, generic manufacturing would significantly lower the price of novel pharmaceuticals. The earnings produced throughout their patent life would more than suffice to finance the necessary R&D for future goods, yet new "blockbuster" drugs would continue to be developed on a regular basis. As a result, the industry as a whole would continue to produce cutting-edge medicines that, after a brief patent life, would be accessible to everyone at reasonable prices.

For the following few years, it appeared that this prognosis would be accurate as numerous new "blockbuster" medications from the R&D departments of many of the large research pharmaceutical corporations routinely entered the market. Sadly, this didn't persist, and it was discovered that simply "turning the handle" of the R&D apparatus would not ensure that any new items would emerge at all, much less a torrent of creative "blockbusters." In actuality, the pharmaceutical business has seen a long-term deterioration in R&D efficiency. Since 1950, the number of new medications approved per billion US dollars spent on R&D has decreased by around half every nine years, or about 80 times when adjusted for inflation. ^[57]

The initial response to these problems by the industry was consolidation, with a number of large and sequential mergers and acquisitions followed by a number of very large ones. The 30 research pharmaceutical companies that existed in 1989 had by 2010 successively merged to become only 9 companies. Pfizer alone had absorbed American Cyanamid, American Home Products, Pharmacia, Upjohn, Warner-Lambert and Wyeth, as well as the pharmaceutical interests of Monsanto.

The goal of this initiative was to maximize the innovation and R&D effort in the two drug pipelines while reducing staff and costs by leveraging the synergy between the partners. The financial markets were quite interested in this activity, but it is now clear that it was difficult to realize the benefits for shareholder value. ^[58] More crucially, there was no corresponding growth in the number of new goods despite significantly expanding R&D efforts. J. P. Garnier, the GSK CEO, finally acknowledged this publicly in 2008. ^[59]

"The leaders of the large firms, particularly those working in the pharmaceutical industry, believed falsely that R&D could be scaled, industrialized, and influenced by precise measurements and automation. The end result is a loss of transparency, self-responsibility, and the enthusiasm of scientists for research and development.

In print a year later, in 2009, Bernard Munos stated what many in the sector had long since known to be true: ^[60]

"The incidence of a handful of "black swan" products at random determines the success of the pharmaceutical sector."

The failure of the "blockbuster" drug model has grave ramifications for the industry's future. The R&D effort must be supported by profits from successful pharmaceutical products, but if new pharmaceutical products aren't developed to take the place of successful ones when their patents expire, it gets harder to keep up the R&D.

Table 2. ^[61] Provides an overview of the issue's scope.

Table 2: Loss of revenue due to patent expiry.

| Company | % Revenue loss in 2010–12 solely due to patent expiry |
|----------------------|---|
| AstraZeneca | 38 |
| Sanofi – Aventis | 34 |
| Bristol Myers Squibb | 30 |
| GSK | 23 |
| Eli Lilly | 22 |
| Merck | 22 |
| Novartis | 14 |

The industry has adopted two different strategies in response to this "patent cliff": first, it has sought to increase its track record of innovation through the acquisition of biotechnology firms, such as Medimmune by AstraZeneca in 2007 for US\$ 16 billion ^[62] and Human Genome Science by GSK in 2012 for \$ 3.6 billion ^[63], as well as a number of other smaller "boutique" businesses. The second method has been to significantly lower operating costs by combining portfolio rationalization, increased collaboration, and widespread outsourcing with direct cost reductions from increased efficiency. As a result, between 2000 and 2010, there were approximately 300,000 fewer positions in the global research pharmaceutical business. ^[64] The rates of innovation have not increased despite these measures.

Environmental Challenges

There have been numerous recommendations in recent years that the pharmaceutical industry start producing "green" drugs in light of the finding of pharmaceutical residues in water. ^[65–67] The subject of what constitutes "green" and the degree to which the current generation of medications is green is thus raised.

The most comprehensive data is now provided through the Swedish environmental classification system. ^[67] This classifies medications into five groups depending on their environmental risk, which is computed using intrinsic hazard data and expected environmental exposure. Although research is ongoing, it is obvious that the vast majority of medications (>97%) fall into the "insignificant" risk category. Another recent study, conducted under the European Union Framework 6 research programmed, yielded a similar result. This noted that a considerable body of literature on the ecotoxicity of medications is now available, and that examination of the data, along with an increasing amount of monitoring and modelling data, indicates that the bulk of pharmaceuticals have negligible environmental concerns.

Despite the fact that the environmental danger is relatively low, numerous pharmaceutical residues can still be discovered in the aquatic environment using sophisticated analytical techniques. As a result, many people continue to put pressure on the pharmaceutical industry to develop "greener drugs," using the precautionary principle. The goal of "greener" drug development is to create drugs that leave less traces in the environment. ^[67]

Because most medications are administered orally, they must be able to pass through the very acidic stomach. Stability is required not only for the treatment to be effective, but it can also result in side effects due to the toxicity of breakdown products, notably in the liver. The perfect medicine would thus be one that began to degrade only after the patient had expelled it.

Producing medications that are more biodegradable in the environment, on the other hand, will not always eradicate environmental residues. The current detection of very low environmental residues represents the equilibrium concentration obtained between a constant intake from wastewater treatment facilities and the rate of degradation in the environment. The data from the Swedish environmental classification scheme ^[68] show that, while very few existing medications breakdown quickly in the environment, very few are also highly persistent, and most pharmaceuticals appear to disintegrate, albeit slowly. ^[69] Increasing the disintegration

rate of new medications would undoubtedly reduce the current residue levels observed in the environment, but residues at lower levels would almost certainly still be identifiable using current analytical methodology.

Nevertheless, by taking this precautionary approach, we hope to lower environmental residual levels as much as we can without endangering patients' health. Our goal is not to create medications that degrade. This can be achieved in a number of ways, one of which is to increase the pharmaceuticals' ability to degrade, though there are other approaches as well.

One of the driving forces behind pharmaceutical research is the need to improve the efficacy of human medications. As a result, research teams are always attempting to increase therapeutic efficacy in patients, and the majority of the changes being consistently pursued in drug discovery and development teams will also result in a lower environmental footprint. Table 3 depicts many pharmaceutical aims that might result in improved patient benefit, as well as the environmental benefits that would result if those targets were met. ^[70]

Table 3: Comparison of criteria for drug design and environmental significance.

| Drug Design Criteria | Environmental Significance |
|--|---|
| 100% Oral absorption | Reduced emissions from patients to drains |
| Metabolized in patient to inert substances | Releases only inert substances |
| Effective in all patients treated | Produce lower overall drug use |
| Disease receptor specific | No impact on healthy receptors |
| No effects other than therapeutic ones. | No non-target effects |

Lower residues of active chemicals entering the environment, or decrease at source, would result from the first three of the conditions stated in the table. The latter two would result in even less possible damage to ecosystems from the remaining active substance.

Candidate medications with a lesser potential for environmental impact are already being developed as a result of current advancements. For instance, lesser doses may be given to produce the same therapeutic benefit if drug metabolism and pharmacokinetics are well understood. Similar to shorter therapy duration, improved drug delivery, better targeting, and enhanced specificity all directly result in reduced environmental residues and smaller emissions from the patient to the environment.

As we've seen, the industry is still dealing with the "blockbuster" method's legacy issues and is also experiencing a drop in the rate of creation. Two technological revolutions, nevertheless, are already in progress and could help to lessen the industry's total environmental impact.

First up is the development of biopharmaceuticals. ^[71] The great majority of medications we currently use are made up of relatively tiny molecules that were created through chemical synthesis. However, as our knowledge of genomes and proteomics continues to progress and our technological capacity to produce very large molecules grows, there is a fast-expanding interest in using biological rather than chemical-based medicines. Synthetic insulin, the first biopharmaceutical, was created by Genentech and marketed by Eli Lilly. By 2013, the US FDA had authorized 300 biological medicines, and 5400 more were undergoing development in the USA alone. Based on global sales in 2012, 7 of the top 10 drugs were biopharmaceuticals ^[72] and it is estimated that this area now accounts for more than 40% of all drugs in development.

The fastest growth is in the area of monoclonal antibodies, which are components of the human immune system and are considered by some to be the perfect human medicines. They have major therapeutic advantages. Their high potency means that patient doses can be small, which subsequently then requires only small-scale manufacture. They have exquisite specificity and can be targeted to human receptor sub-types responsible for pathology or disease; thus, they have substantially less potential for side effects. These proteins are then rapidly metabolized by the human body to produce fragments with no mammalian biological activity, thus avoiding the possibility of producing metabolites with undesirable pharmacological activity. From an environmental perspective these substances appear to offer major advantages; most of these compounds produce little if any residues of the active substance, which is in any case much less likely to exert any adverse impact on the ecosystem, since it is specifically designed to interact only with a diseased human receptor. However, the full environmental relevance of these substances is not yet clear. Biopharmaceuticals are not all easily biodegraded, and modified natural compounds even less so. Structurally related compounds such as plasmids have already been detected in the environment and it is known that the protein structures known as prions are very environmentally stable. ^[73]

The second therapeutic revolution also stems from our improved understanding of genomics, although it is still in its infancy. This is the area of "personalized medicine". ^[74] It has been known for many years that most pharmaceuticals do not work successfully in all patients. It was suspected that this was due to the slightly different genetic make-up of individual patients, but lack of appropriate experimental techniques meant that this could not be further investigated. However, the recent rapid advances in the mapping of the human genome and subsequent development of the scientific disciplines of genomics, proteomics and metabolomics is leading us to a better understanding of the molecular signals of many diseases. The expectation is that molecular screens combined with clinical data will point to more precise treatment options for each patient sub-group. This should enable much more precise and effective prescribing to occur which will, in turn, mean less overall drug use, since every prescribed dose will be effective first time.

Conclusion:

There are still many issues plaguing the research pharmaceutical sector, and the most of them don't seem to have simple fixes.

Despite having the sole right to sell a new drug for the duration of its patent life, increasing regulation is increasing costs and delaying the time it takes for a patent to expire; executive management teams are becoming more risk-averse, which is slowing the development of novel pharmaceuticals; and patient populations and regulatory bodies are becoming less risk-tolerant, which is resulting in a lower success rate for marketing authorization. Moreover, a lot of people believe that the existing research pharmaceutical business model is unsustainable, but no new model has yet to be developed.

The next generation of human pharmaceuticals, however, will leave substantially less residues in the environment than those that occur from the usage of existing medications because of the increasing dominance of biopharmaceuticals in drug-development pipelines.

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