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SMALL BUSINESS PHARMACEUTICAL INDUSTRY

Mumtozbegim Kholmatova
PhD. Student,
Tashkent State University of Economics

ANNOTATION
Small businesses are corporations, corporations, or sole proprietorships that have fewer employees and less annual income than a conventional business or corporation. The pharmaceutical industry has a number of unusual features, both in its structure and in the nature of business operations, little known outside the industry, but having a significant impact on the process of bringing new drugs to the patient. The research and development process with all its problems, including environmental ones, is described.

Keywords: small business, pharmaceutical industry, chemical, physical, structural or biological similarity.

ANNOTATSIYA
Kichik biznes - korporatsiyalar, korporatsiyalar yoki yakka tartibdagi tadbirkorlar bo'lib, ularda ishchilar soni va yillik daromadi oddiy korxona yoki korporatsiyadagiga qaraganda kamroq. Farmatsevtika sanoati o‘zining tuzilishida ham, xo‘jalik operatsiyalari xarakterida ham bir qator noodatiy xususiyatlarga ega bo‘lib, ular tarmoqdan tashqarida kam ma’lum bo‘lgan, ammo bemorga yangi dori vositalarini olib kelish jarayoniga sezilarli ta’sir ko‘rsatadi. Tadqiqot va ishlanmalar jarayoni uning barcha muammolari, shu jumladan ekologik muammolar bilan birga tavsiflanadi.

Kalit so’zlar: Kichik biznes, farmaseftika sanoati, kimyoviy, fizik, tarkibiy yoki biologik o'xshashliklar.

АННОТАЦИЯ
Малые предприятия - это корпорации, корпорации или индивидуальные предприниматели, в которых количество сотрудников и годовой доход меньше, чем в обычном предприятии или корпорации. Фармацевтическая промышленность имеет ряд необычных особенностей как по своей структуре, так и по характеру хозяйственных операций, малоизвестных за пределами отрасли, но оказывающих существенное влияние на процесс доведения новых лекарств до пациента. Описывается процесс исследований и разработок со всеми его проблемами, в том числе экологическими.

Ключевые слова: малый бизнес, фармацевтическая промышленность, химическое, физическое, структурное или биологическое сходство.

Introduction

The pharmaceutical industry has a number of unusual characteristics that make it very different from what people normally think of as industry. The development of a new pharmaceutical is very time consuming, extremely costly and high risk, with very little chance of a successful outcome. It is also an industry replete with contradictions; for example, despite the undisputed fact that for over a century the industry has made a major contribution to human wellbeing and the reduction of ill health and suffering, it is still regularly identified by the public in opinion surveys as one of the least trusted industries, often being compared unfavourably to the nuclear industry. It is undoubtedly one of the riskiest businesses in which to invest money, yet it is perceived by the general public to be excessively profitable. The major pharma companies rightly promote themselves as being research-based organisations, yet most people believe that they spend more on marketing than on research. Despite the acknowledged risks and costs associated with pharmaceutical development, many citizens still believe that pharmaceuticals should be being developed to meet all human needs and that when developed they should be given away to everyone on the basis of need. This opening chapter aims to provide a basic understanding of how the industry works and attempts to provide an explanation for some of its contradictions. The objective is to provide a backdrop to the business so that the challenges of the issue of pharmaceuticals in the environment can be better understood. Note that the words “medicine,” “pharmaceutical” and “drug” are often used interchangeably and the word “drug” can also mean both a medicine and an illegal substance, depending on the context. In this chapter the word “pharmaceutical” is arbitrarily assigned to the end-products of the pharmaceutical industry that are used by patients. The word “drug” is mainly used for potential pharmaceuticals whilst under development by the industry. Historical Background Human beings have been using “drugs” to treat illness and disease for more than 3000 years. A few dozen drugs of plant and animal origin were already recorded in China around 1100 BCE and by the end of the 16th century the Chinese were using at least 1900 different remedies. Today Traditional Chinese Medicine recognises more than 13 000 drugs. Outside China, the first known pharmacopeia, the five volumes of De Material Medica, were written in the first century CE by Dioscorides, a Greek botanist.4 Herbal practitioners of this early period have been identified in many indigenous populations across the globe, such as North and South America, India and Australia. In the later mediaeval period, herbalism flourished in both the Islamic and Christian parts of the world. This tradition continued up to the 17th century, encompassing the work of Paracelsus in Switzerland and Culpepper11 in

England. Culpepper's work, The English Physician, published in 1652, was one of the first English language pharmacopeias. Until the 18th century the use of herbal medicines had been entirely based on empiricism: practitioners knew what worked but not why or how. However, in the late 18th century the foundations of pharmacology, the study of the actions of drugs and how they exert their effects, began to emerge. William Withering in the 1780s was one of the first people to study and isolate the active ingredient in a herbal remedy. He isolated digitalis from the foxglove, describing its extraction from various parts of the plant, its subsequent effects and the optimum way of using it to treat patients. Before the 19th century, chemists had generally believed that compounds obtained from living organisms were endowed with a "vital force" that distinguished them from inorganic compounds. However, in 1828 Friedrich Wo¨hler produced the organic chemical urea, a constituent of urine, from the entirely inorganic compound, ammonium cyanate. Although Wo¨hler was always cautious about claiming that he had disproved the theory of vital force, this event has often been thought of as the starting point of organic chemistry.

How to Start a Pharmaceutical Distribution Company?

These two scientific developments in pharmacology and organic chemistry led, amongst other developments, to the foundation of the pharmaceutical industry in the last decade of the 19th century. The modern pharmaceutical industry can trace its origin to two main sources: companies such as Merck, Eli Lilly and Roche that had previously supplied natural products such as morphine, quinine and strychnine, moved into large-scale production of drugs in the middle of the 19th century, whilst newly established dyestuff and chemical companies, such as Bayer, ICI, Pfizer & Sandoz, established research labs and discovered medical applications

for their products. Nevertheless, growth was relatively modest and at the start of the 1930s most medicines were still sold without a prescription. Almost half of them were compounded locally by pharmacists and in many cases physicians themselves dispensed medicines directly to their patients. However, a number of major advances were made in the early part of the 20th century. Salicylic acid, a natural constituent of willow bark, had been recorded by Hippocrates as having analgesic properties. In 1897, scientists at Bayer demonstrated that a chemically modified version of salicylic acid had much improved efficacy and the product, aspirin, is still in widespread use today.16 In the 1920s and 1930s both penicillin and insulin were identified and manufactured, albeit at a modest scale. The Second World War provided a major stimulus to the developing industry, with requirements for the largescale manufacture of analgesics and antibiotics and increasing demands from governments to undertake research to identify treatments for a wide range of conditions. After the war, the implementation of state healthcare systems in Europe, such as the UK's National Health Service (NHS),17 created a much more stable market, both for the prescription of drugs and, much more importantly, their reimbursement. This produced a major incentive for further commercial investment in research, development and manufacture. This greater role for the state was paralleled on both sides of the Atlantic, with increasing government regulation of medicine production. The post-war period from the 1950s to the 1990s saw major advances in drug development with the introduction of new antibiotics, new analgesics, such as acetaminophen and ibuprofen, and complete new classes of pharmaceuticals such as oral contraceptives, ß-blockers, ACE inhibitors, benzodiazepines and a wide range of novel anti-cancer medicines. The thalidomide scandal of 196118 triggered a complete reassessment of state controls on the industry. New regulations now demanded proof of efficacy, purity and safety, with the latter leading to a massive increase in the requirements and costs of research and development, particularly in the clinical testing of new drugs.19 As the barriers to entry in drug production were raised, a great deal of consolidation occurred in the industry. Likewise, the processes of globalisation, which had begun before the war, increased. This resulted in new drug development being dominated by a small number of very large multi-national companies and the beginning of the era of the "blockbuster" drug. What is a Pharmaceutical? This may seem an odd question since we all surely know what a pharmaceutical is. However, there is no straightforward scientific answer to this apparently simple question. Pharmaceuticals are not a class of substances like phthalates or PCBs. They have no chemical, physical, structural or biological similarities. There is thus no scientific justification for treating pharmaceuticals collectively as a coherent set of chemical substances. Pharmaceuticals are often thought of as being complex chemical structures but they can also be simple aromatic molecules like the anaesthetic,

propofol (2,6-diisopropylphenol), simple aliphatic molecules like the vasodilator, nitroglycerine (1,2,3-trinitroxypropane), or more complex but still relatively low molecular weight molecules like the statin, atorvastatin (MW 558.6) ((3R, 5R)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-propan-2-ylpyrrol-1-yl]-3,5-dihydroxyheptanoic acid). Increasingly, new pharmaceuticals are likely to be very high molecular weight biopharmaceuticals such as insulin (MW 5800 Da). The Pharmaceutical Industries As far as most people are concerned, the Pharmaceutical Industry consists of a small number of very large multinational corporations with household names such as AstraZeneca, GlaxoSmithKline (GSK), Eli Lilly, Merck, Novartis, Roche and Pfizer. These companies are collectively known as Big Pharma, a phrase that is intended to be prejudicial.46 However, this is very misleading. If you ask a member of the public if they have heard of Teva or Mylan there is a high probability that they will have never heard of either of them, despite the fact that Teva is the 11th largest pharmaceutical company in the world47 and may very well be supplying the medicine that they are currently taking. Research, Discovery and Development We saw in Section that almost any substance has the potential to find use as a pharmaceutical, but how do we know which ones to use? In the days of the herbalist and apothecaries, knowledge was derived from simple empiricism, substances were used when they had been shown to work, and such valuable information was passed on in oral tradition until documentation became available. However, although at the beginning of the 21st century we have far more knowledge than the first century herbalists had, the process of identifying new drugs is, at least in principle, very similar. The following recent quote from a medicinal chemisty is apposite: “In medicinal chemistry we’re still fundamentally an observational science. (That should have been obvious given how little math any of us need to know). We have broad theories, trends, rules of thumb – but none of it is enough to help us very much, and we’re constantly surprised by our data. That can be enjoyable, if you have the right personality type, but it sure isn’t restful, and a lot of the time it isn’t very profitable, either”. The following section provides a simplified overview of the process involved in developing a new pharmaceutical. In view of the low success rate, the R&D departments of research pharmaceutical companies will not just be investigating one drug but, at any one time, will be looking at many different substances at varying points in the development cycle. A large company may have 100–200 substances going through its development pipeline at any one time.52 Pre-clinical Trials Identifying a new drug starts with research into the particular illness or disease of interest. This can be being undertaken within the research laboratories of the pharmaceutical company but may also be being carried out in academia, government research organisations, small “boutique” pharmaceutical companies or any combination of these. Medical research is now so complex that large pharmaceutical companies currently undertake most of their

research in combination with partners. In those situations where the research identifies a specific receptor or target within the body which could deliver beneficial effects, the search can begin for a potential drug. The target can be a wide variety of things: a particular cell type, enzyme, gene, pathway or process. It is estimated that more than 500 targets are currently under investigation in the research pharmaceutical companies. Once a target has been selected, the next step is to identify any substances that might have some sort of regulating effect on it. Advances in automated chemical synthesis techniques, such as combinatorial chemistry, have enabled chemical libraries to expand rapidly.

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