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DRUGS DISCOVERY AND DEVELOPMENT SCENARIO IN INDIA

Health Science

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ABSTRACT

Drug discovery and development is the journey of identifying new chemical and biological compounds against any specific diseased condition and transforming them into commercially available products. The whole process takes almost 8-15 years from conceptualizing the idea to the final products in the market. There are several steps involved but broadly it can be divided into three major steps which include drug discovery, drug development, and commercialization. Identification of candidate compounds, their synthesis, screening, and evaluation of safety and efficacy are some of the major milestones. Once compounds exhibit some efficacy and stability, they are run through various clinical trials to establish their safety in animals and later in humans. This whole process is lengthy and very expensive. As per the reports, any molecules from the conceptualizing stage to the commercializing stage take around 1B$. Time is the essence in drug discovery programs therefore many organizations run projects at various sites in collaboration to expedite the whole process. In India, many government agencies are involved and sponsor new drug discovery programs. Several private organizations in India also invest millions of dollars to establish the best-class facilities which attract many global clients in India to run integrated drug discovery (IDD) programme in fast and cost-effective way. Indian governments foster the environment to cultivate the drug discovery program which not only supports the current GDP but also provides an opportunity to new researchers in India and to start a career in this field.

KEYWORDS

drug discovery, drug development, India, compounds etc.

INTRODUCTION

Drugs are chemicals with low molecular mass interact with macromolecular targets and produce a biological response. These medicines use in diagnosis, prevention and treatment of ailments. Drug and target interaction is an important aspect of drug discovery, it defines the recognition of interaction between drug compound and the targets in the human body. Proteins which perform the role of biological catalysts in the body are called enzymes and those which are important to the communication system are called receptors.

Historical Background Of Medicine

Ayurvedic knowledge originated in India more than 5,000 years ago and is often called the "Mother of All Healing." In India, the use of plants to make medicines are also mentioned in the Rigveda, The Atharva Veda and Yajurveda. Ayurveda is medicine with intelligence and more effective for chronic diseases and prevention. There is a need to interpret and merge principles of Ayurveda when, adopting modern science tools in drug development and validation. The Indian system of medicine is divided into many like Ayurveda, Siddha, Unani, Allopathy and Homeopathy etc and each stream has their own theory, principles, methods and applications. But the best method among all is the validation of a combined (Ayurveda and modern medicine) therapeutic approach. With superior efficacy and safety. This approach is likely to be a major leap in overcoming to treat difficult chronic disorders like Cancer, diabetes, arthritis etc. COVID-19, a global pandemic has affected individuals all over the world. It was very evident that how beautifully Indian people are dealing with the pandemic with a combing approach of Ayurveda and modern medicines. Ministry of Health and Family Welfare, Directorate General of Health Services (EMR division) has also issued post-COVID management protocol which includes Immunity boosting ayurvedic medicines like Ayush Kwatha, Samshamani Vati or Guduchi powder, Ashwagandha powder, Aamalaki fruit or Aamalaki powder, Yashtimadhu powder, warm milk with Haridra powder and gargling with turmeric and salt under the direction of registered Ayurveda physician [1].

Modern System Of Medicine

In India, the concept of modern drug discovery has been started since the beginning of 20th century. The first drug (Urea stibamine) was synthesised at Campbell Medical School in Kolkata in the year 1922 by Upendranath Brahmachari which was found to be very effective against kala-azar (visceral leishmaniasis)[2]. After the success of Urea stibamine, the Indian Government has taken the initial steps to strengthen the drug discovery and development procedure through the establishment of new research institutes like CSIR-CDRI (established in 1951), fully dedicated for drug related research activity. Its major role was to identify the new candidate compound from natural products and to synthesise them. A major breakthrough was achieved after synthesizing the world's first non-steroidal oral contraceptive pill "Saheli" by CSIR-Central Drug Research Institute (CDRI) in 1991[3]. In line of this, an oral rehydration therapy (ORT) which a combination of drinking water mixed with controlled amounts of salt and sugar, considered as the most important medical advance of the 20th century was first discovered by H. N. Chatterjee from Calcutta. This synthesis didn't get much importance that time but years later it was again rediscovered in 1968 by European scientists and become a famous remedy for loose motion and diarrhea [4, 5].

The premier Institutes like IISC Bangalore, TIFR Mumbai, NCL Pune plays major roles in drug molecule characterisation techniques and in drug development process. Several years of research, on the pharmaceutical use of medicinal plants has led to the transformation of natural products into modern synthetic drugs used widely [6]. Earlier Indian people use plant and their parts (stem, roots, leaves, flower etc), animal products, marine life, minerals, clay, soil and many more for cure of diseases [7,8]. India ranked 10th in plant rich countries in the world and also known as (Botanical Garden of the world) [9]. In the 20th century, modern techniques for separation, structural determination and screening made easy to understand the structure activity relationship of drugs and make it a convenient to use natural products for drug discoveries process [10,11]. After that, era of antibiotics and sulphonamides drug had taken a lead in the field of drug synthesis. Some remarkable discoveries reported from other public laboratories are Enfenamic acid, an anti-inflammatory agent (IICT, 1980) and Risorin, a combination preparation for tuberculosis (IIIM, 2009) [12,13].

In the process of drug discovery, among the several candidate compounds, only 10-15 percent are able to pass all the stages of development process satisfactorily and reach to the marketing and application [14]. Several pharmaceutical companies are also collaborating with multinational companies and developing bioactive molecules with them. Indian government is also providing various grants to promote the development of new drugs. Another important aspect is to document the cases and publish the case study in some good scientific and medical journals to establish it as evidence-based medicine on global platforms. This review paper is comprehensively focused on the workflow for Drug Discovery, current scenario of Drugs Discovery and Development in India and to shedding light on the major challenges to modern drug discovery in a developing country like India.

Workflow For Drug Discovery

Drug Discovery and Development Pathway is a tedious process and involved many steps from basic research to post-market surveillance which take time, skilled manpower, technical competency, laboratory facilities, money etc for a new commercial product to the marketing. Every step has many subsets under which new drug development program runs. The Figure 1 clearly depicted the many stages of drug discovery process.

Early drug discovery	Preclinical studies	Clinical development	Food and Drug Administration (FDA) Review	Post market monitoring
Target identification and validation	In vivo and in vitro	Phase1-healthy volunteer study	-	FDA adverse event reporting system
Hit discovery	Proof of concept	Phase 2 and Phase 3-Studies in patient population	FDA approval	
Assay development and screening	Drug delivery	Dose escalation, single ascending and multiple dose studies	Drug registration	
High throughput screening	Formulation and optimization	Safety and efficacy		
Hit to lead	Dose range finding	Pharmacokinetics analysis		
Lead optimization	IND application	Bioanalytical method development and validation		

Figure: 1 Various Steps and sub steps involved from drug discovery to the post market monitoring

Source: https://www.nebiolab.com/drug-discovery-and-development-process/

Drug discovery and development pathway includes from the design a compound to stop or reverse the effects of the disease, done various test of target molecule to get best beneficial effects against the diseases, to compare the side effects with similar existing compound (if any), applied the latest and technologies. All these testing procedures, identify the candidate compounds which looks promising for that particular disease with no or minimal side effects. The discoverer institution then collects information about the compound like: its absorption, distribution, metabolism and excretion in the body, its mechanisms of action, potential benefits, doses, side effects, its interaction with other drugs etc. Then, the drug enters into another stage of preclinical and clinical development. Preclinical research trial has two types: In vitro and In vivo, Usually, preclinical studies provide detailed information about the right drug doses and their toxicity levels. Based on the data, one gets from preclinical testing, researchers review their findings and took decision for their further trial on human being. The next step is clinical research" refers to studies done in human being of different ages and groups, so they are conducted in many stages according to the number of volunteers and drug doses. After the clinical trials, all phases study, a researcher found the clear picture about the safety, dosage efficacy, side effects and adverse reactions on human being. Lots of data about drug has been collected from clinical trials. The New Drug Application (NDA) includes every information regarding drug before getting the marketing permission like drug abuse information, patent information, safety updates, labelling and direction for usage. After reviewing the data and find the satisfactory result, the regulatory authority gives the permission for marketing for the safe and effective for its intended use. In India, there are Governmental acts like THE DRUGS AND COSMETICS ACT, 1940 (23 OF 1940) (As amended up to the 31st December, 2016) and THE DRUGS AND COSMETICS RULES, 1945 (As amended up to the 31st December, 2016) which a drug developer or institution has to follow before any action [16].

Challenges In Drug Discovery

Drug discovery and development is a complex, costly, lengthy and ongoing procedure. Drug discovery is a process by which novel effective medicines are identified by a series of critical research activities and many scientific branches like, pharmacology, medicinal chemistry and biochemistry. A successful drug discovery strategy relies on understanding patient need, target disease as well as current and future competition. Nowadays, researchers in India have to tackle with many hurdles. In India, the main challenge is to provide their traditional medicine a strong scientific base and develop research technical competency to regularly synthesised new and effective drugs based on advancement in modern biological sciences [17].

The Indian pharmaceutical industry has made high strides since 1970-80 because of the revised patent law which permitted manufacturing & marketing of patented new chemical entities by alternative, non-infringing processes. Despite several advancements and huge investments, we are far behind in this area of research. The formation of the WTO in 1995 and the obligation of the member countries to comply with the TRIPS provisions has also fastened this business. Some of the progressive Indian companies pioneered this transition in the last decade by initiating drug discovery programs in-house and these efforts has gained success [18].

Science and technology field in India has achieved significant advancement yet the drug discovery and development journey are facing numerous challenges at every stage. The first and main challenge is the shortage of technical competency and efficiency of man power. Indian researchers went to the developed countries for higher education in science & technology and for better career prospects. According to an estimate by the Organization of Pharmaceutical Producers of India (OPPI), more than 15% of the scientists engaged in Pharmaceutical R&D in the U.S. are of Indian origin. The Indian Patent Act of 1970, which is mainly focused for the generics drugs marketing, affordable to developing countries, done major cost cutting to discover new medicines which result in the loss of skill [19]. A recent industry survey estimated that 66% of the existing manpower is not ready for industry, highlighting the misfit between academic training and industry needs [20]. Some recent reports have concluded that how we can strengthen our weaknesses by improvising our bad infrastructure, laboratory facilities, quality of teaching, bureaucracy and political influence in the scientific education system [20-23]. Cost efficiency is also a problematic challenge to control.

There are, some other challenges which need to be addressed properly apart from man power like Length, complexity, uncertainty of drug success, cost of drug discovery, limitation of animal models and many more. Lack of validated diagnostic and therapeutic biomarkers to detect and measure biological states and unaware of current regulatory processes for investigational new drug (IND) applications is also includes in a list of challenges [24]. Overall investment in R&D, and more specifically in a New Chemical Entity (NCE) drug discovery, needs to be increased, as it significantly behind global industry average. More drug companies and research institutes specially for drug development need to be estabilised and funded properly. If we compare the data of India (developing country) and America (developed country, there are more than 40 pharmaceutical companies and an estimated 1700 biotech companies established in America which is far behind when compared to India's life sciences landscape [25]. These obstacles can be getting better off by making stronger links between institutions, active in life sciences R&D, biotechnology and pharmaceutical companies has given great benefits. The Indian Government has made a goal to stimulate the launch of 2000 startups in life sciences over the coming five years [26]. Out of many new candidate compounds from target identification and validation to lead optimisation, only 12-15 % of compounds can enter clinical trials [27]. India has already set a highly ambitious goal: Pharma Vision 2020 in 2010 to have one out of five to ten new drugs discovered in the world originating from India by 2020 [28] which would have represented an average of at least three to six new medical entities (NMEs) per year but still highly ambitious target of "one NME per year and 10–12 incremental innovation launches per year by 2030 [29]. Preclinical testing is a very important step for the assessment of a potential drug's safety, efficacy, and pharmacokinetics and the predictability of preclinical models for adverse drug reactions and long-term toxicities is also a challenge [30]. From target identification to post-marketing, every stage presents face its unique set of challenges. To overcome these challenges, collaboration is must needed among researchers,

pharmaceutical companies, regulatory agencies, and other stakeholders, so the journey of drug development become more effective, smooth, cost effective and most importantly produce novel drugs by latest technologies to reach its ultimate goal: benefitting people in need from different diseases.

Government Support For Pharmaceutical Research

The Indian government provides a range of support for pharmaceutical research, including collaborative R&D projects, grant-in-aid projects, national facility projects, funding for research, skill development, infrastructure support, intellectual property support, tax breaks, weighted tax deduction, funding for R&D, infrastructure support, capacity building, intellectual property rights facilitation, international cooperation, tax incentives and grants for biotech start-ups and firms seeking to expand, exemption from VAT and other fees, financial assistance with patents, and subsidies on investment, land, and utilities .

Current Scenario In India

The Indian pharmaceutical industry is expected to reach $65 billion by 2024 and $130 billion by 2030 (31). Indian companies have been actively involved in proprietary drug discovery and development efforts between 1994 and mid-2016.

The "New Economic Policy" of 1991 has become a turning point for the drug industry in India. This policy was mainly made for liberalizing economic operations and joining the WTO (World Trade Organization) in 1995. The signatures on the agreement on TRIPS (Trade Related Aspects of Individual Property Rights) with a 10-year transition period from 1995 to 2005 & the amendments in the Indian Patents Act 2005, opened Indian doors to the new drug product patents and in turn to the world of pharma innovations [2].

Despite all the hurdles we discussed earlier in the process of drug discovery and development procedure, India holds a significant place in world pharmaceutical market. The value of drug industries in India is about to reach USD 120 billion by 2030. India supplies 62% of global demand for vaccine and became world's largest vaccine producer, Government of India has also started "Jan Aushadhi Kendra" all over the country to produce generic drug for people at generic rate [1]. In the current perspective, Indian pharmaceutical industry is recognized as a global leader in the production of generic drugs and is ranked third in terms of manufacturing [9]. India's national regulatory agency for drugs is Central Drugs Standard Control Organisation (CDSCO). Every country has their regulatory agencies like European Medicines Agency of the European Union, Food and Drug Administration (FDA) of the United States, Medicines and Healthcare products Regulatory Agency of the United Kingdom, and the State Administration for Market Regulation of China [32].

Pharmaceutical companies involved in R&D are of three types: development of new chemical entity (NCE), Modification in existing NCE and to develop novel methods for drug discovery. Indian Pharmaceutical companies are doing great in the production of generic drugs [14]. They have discovered more than 120 new entities which are under the preclinical and clinical trials stages for example Saroglitazar (Lipaglyn) for diabetic patients, Synriam for malarial etc. [33]. Apart from pharmaceutical firms, various governmental department has also come forward and took initiative towards drug discovery like Open-Source Drug Discovery (OSDD) by Council of Scientific and Industrial Research (CSIR), Biotechnology Industry Partnership Programme (BIPP) by Department of Biotechnology, Government of India. Among many initiative OSDD is an entirely new approach as an open-source mode which provide a broad platform so the R & D all over the world can collaborate and discuss the best solutions and new methods/drugs for neglected diseases [34]. Drug discovery by these governmental institutions has given some significant output as they discovered some important drugs and formulations. The complied list of some drugs is given in Table 1.

Table 1: List Of Some Drugs Developed In India (1921-2023)

Drug	Year	Application	Discoverer institution
Urea Stibamine	1921	Kala-azar	Trop. Mad., Calcutta
Methaqualone	1956	Hypnotic	R.R.L., Hyderabad &K.G.M.C., Lucknow
Peruvoside	1958	Cardiotonic	C.D.R.I., Lucknow
Hamycin	1961	Antifungal	HAL., Pune
Centimizone	1972	Anti-thyroid	C.D.R.I., Lucknow
Sintamil	1976	Anti-depressant	Ciba-Geigy, Bombay
Tromaril	1980	Anti-inflammatory	R.R.L., Hyderabad
Nonaperone	1980	Anti-psychotic	Novartis, Mumbai
Amoscanate	1980	Anti-parasitic	Novartis, Mumbai
Enfenamic acid	1982	Anti-inflammatory	Unichem Laboratory, Mumbai
Isaptent	1985	Pregnancy termination	C.D.R.I., Lucknow
Nancy Kit	1985	Pregnancy detection	HAL., Pune
Cibemid	1986	Anti-protozoal	Ciba-Geigy, Bombay
Gugulipid	1986	Hypolipidemic	C.D.R.I., Lucknow
Filaria	1986	Diagnostic kit	C.D.R.I., Lucknow
Centbucridine	1987	Local anaesthetic	C.D.R.I., Lucknow
Centbutindole	1987	Neuroleptic	C.D.R.I., Lucknow
Centchroman	1990	Contraceptive	C.D.R.I., Lucknow
Chandonium iodide	1994	Neuro-muscular blocker	CDRI, Lucknow and Panjab University, Chandigarh
Cent-propazine	1996	Anti-depressant	CDRI, Lucknow
Bulaquin	1996	Anti-malarial	CDRI, Lucknow
Bacosides	1997	Memory enhancer	CDRI, Lucknow
Arteether	1997	Anti-malarial	CDRI, Lucknow
Elubaquin	1999	Anti-relapse anti-malarial	CDRI, Lucknow
Bacosides enriched standardized extract of Bacopa	2002	Memory improvement	CDRI, Lucknow
Consap	2004	Spermicidal cream	CDRI, Lucknow
Risorine	2009	Anti-tubercular	IIM, Jammu
Synriam	2011	Anti-malarial	Ranbaxy, Delhi
Lipaglyn	2014	Diabetic dyslipidemia	Zydus Cadila, Ahmedabad
Dalzbone	2015	Rapid Fracture Healing	CDRI, Lucknow
Joint Fresh	2018	Osteoarthritis	CDRI, Lucknow
GreenR	2023	DNA Gel Stain and RT-PCR Master Mix	CDRI, Lucknow
UniQ	2023	Universal quencher for Nucleic acid Research and diagnostics	CDRI, Lucknow

Table compiled from data collected from different sources [34-36].

Challenges Faced by the Pharmaceutical Industry in India

The major challenges faced by the pharmaceutical industry in India include regulatory compliance and quality standards, intellectual property rights issues, price controls and market dynamics, global supply chain disruptions, research and development challenges, demand forecasting and price fluctuation assessment, strategic execution challenges, digitization and shifting market trends, accurately analyzing dynamic customer preferences and fluctuating prices, managing risks within the manufacturing process and quality systems, inventory management, lack of funding, difficulty in securing government grants, reluctance of venture capitalists to invest, and dependence on imports for active pharmaceutical ingredients (APIs) .

Opportunities for Growth and Innovation in the Pharmaceutical Sector in India

The opportunities for growth and innovation in the pharmaceutical sector in India include increasing demand for generic medicines, growing demand for vaccines, opportunities in contract research and manufacturing, growing demand for biosimilars and biologics, opportunities in digital health, growing demand for medical devices, opportunities in research and development, opportunities for foreign investment, opportunities for partnerships and collaborations, automation and digitization, sustainable practices, quality enhancement, end-to-end data traceability.

Major Players In The Indian Pharmaceutical Industry

Some of the major pharmaceutical companies in India include Pfizer,

Sun Pharmaceutical, Cipla, Divi's Lab, Dr. Reddy's Laboratories, Zydus Lifesciences, Mankind Pharma, Ajanta Pharma, Torrent Pharmaceuticals, Lupin, Glenmark Pharmaceuticals, Systopic Laboratories, Piramal Pharma, Abbott, Alkem Laboratories, Biocon, Ventus Pharma, Emcure Pharmaceuticals, Cadila Healthcare Limited, and Alembic Pharmaceuticals**.**

Research Institutes Involved In Drug Discovery In India

Some of the major research institutes involved in drug discovery in India include the Center for Drug Discovery (CDD), Indian Institute of Integrative Medicine (IIIM), National Institute of Child Health & Development Research (NICH&DR), Delhi, and National Institute for Research in Digital Health and Data Science (NIRDH&DS), Delhi.

The drugs developed by CDRI are available in the Indian market but not either one has been registered in the developed countries. The main restriction of the drug development programme of governmental institution is the lack of commercial approach which could only be possible with the collaboration with the multinational firms. The product patent protection in India under the Patents and Designs Act, 1911 did not have any positive effect because the MNCs, who held the patents were not keen on manufacturing (and R&D) activities in India. So, nowadays, the most important change which has taken place in India for marketing of drugs globally is in a form of Public-Private Partnership (PPP) [38].

CONCLUSION

The drug discovery and development in India has a bright future. To speed up drug discovery, Government of India needs multidimensional efforts along with multinational venture. The success in this field can only be achieved by the combination of our old medicinal approaches with the advanced technologies. Researcher must standardise and improve their drug discovery and development processes to ensure innovation continues at pace in a cost-effective and sustainable manner. To promote research and innovation in drug discovery programme, there is urgent need to make stronger links between institutions, active in life sciences R&D, biotechnology and pharmaceutical companies will give great benefits.

Conflict Of Interest

The authors declare no conflict of interest.

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