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Pharmacovigilance in The Pharmaceutical Industry: An Overview

[1]Mr.Vitnor Pravin Sanjay, [2]Asst. Prof . Gaikwad Vishal

[1]B. Pharmacy Student, Pratibhatai Pawar College of Pharmacy Shrirampur, Ahmednagar, Maharashtra, India
[2]Department of Pharmaceutics, Pratibhatai Pawar College of Pharmacy Shrirampur, Ahmednagar, Maharashtra, India

ABSTRACT

Now-a-days herbal lipsticks are gaining popularity because natural cosmetics are safe to use and easy to handle by women. Synthetic coloring agents may cause allergic reactions and were found to be carcinogenic in nature. Aim of our study was to formulate and evaluate herbal lipstick using natural edible coloring matter like cinnamon bark powder, turmeric powder, cocoa powder as a coloring agent. Along with different natural ingredients such as bees wax, butter, coconut oil, olive oil, castor oil, Vanilla & rose essence and lemon juice were used to formulate herbal lipstick. Prepared herbal lipstick were evaluated for different evaluation test such as color, texture, pH, melting point, breaking point, softening point, surface anomalies, ageing and perfume stability and also compared with marketed standard formulation. Results showed that, different evaluation parameters of prepared herbal lipstick were resembled with standard values and with marketed formulation. Study revealed that, natural edible colouring matter may be the better option for preparation of herbal lipsticks

Introduction

Pharmacovigilance has been defined as the process of identifying and responding to drug safety issues and has grown considerably as a discipline over the past 10 to 15 years. An educational survey in 1994 revealed that more than 320 people currently worked in company pharmacovigilance functions in the UK alone. Pharmaceutical companies are international, hence the number of staff working in this field within the industry, particularly in other European countries and the USA, is far greater. A major pharmaceutical company such as Astra has over 100 permanent, experienced staff in pharmacovigilance within its research and development organisation in Sweden and the UK and a similar number in local operating companies worldwide. This development has been driven by an increased recognition of the role of pharmacovigilance, the investigation and marketing of a wider range of diverse medicinal products and more stringent and detailed regulatory requirements. The number of individual reports of possible adverse drug reactions (ADRs) can be considerable, for key marketed products often more than 1000 case reports a year are received worldwide from health care professionals and other sources.

The aims of pharmacovigilance within the industry are essentially the same as those of regulatory agencies; that is to protect patients from unnecessary harm by identifying previously unrecognised drug hazards, elucidating pre-disposing factors, refuting false safety signals and quantifying risk in relation to benefit. Although the perspectives of companies and the regulatory agencies may be different they now work more and more closely together and share information.

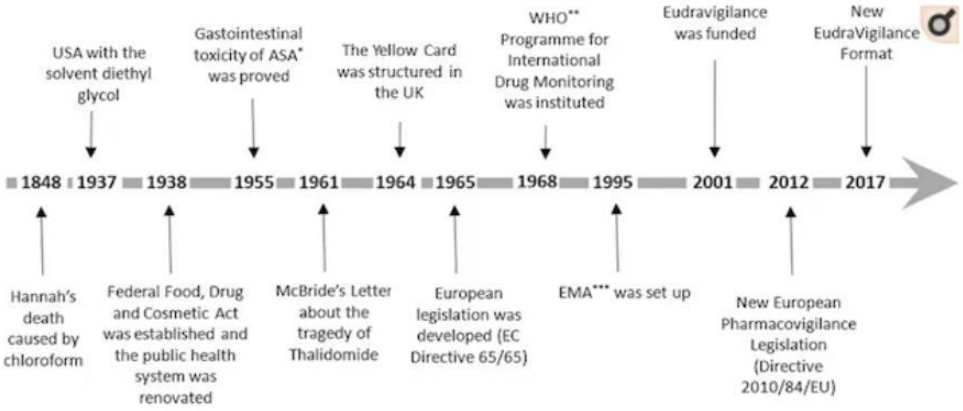
History of Pharmacovigilance:

Pharmacovigilance started about 170 years ago, although it was not yet named as such at that time. The historical phases help us to understand why pharmacovigilance helped us to achieve such important results for man's health and for pharmacology itself, and to identify the challenges that await Pharmacovigilance in future years. In this blog we will see the milestones that led to the evolution of Pharmacovigilance activities in the last century.1848 - 15-year-old patient died in course of routine anaesthesia with chloroform. The patient had problem of ingrown nail of toe; and was given chloroform to remove it and it caused fibrillation of ventricles which resulted in patient death.

- ***The Thalidomide Tragedy (1957-1961) –***

Thalidomide first entered the German market in 1957 as an over-the-counter remedy, based on the maker's safety claims. They advertised their product as "completely safe" for everyone, including mother and child, "even during pregnancy," as its developers "could not find a dose high enough to kill a rat." By 1960, thalidomide was marketed in 46 countries. Around this time, Australian obstetrician Dr. William McBride discovered that the drug also alleviated morning sickness. He started recommending this off-label use of the drug to his pregnant patients, setting a worldwide trend. Many children in the 1960's, like the kindergartner, were born with phocomelia as a side effect of the drug thalidomide, resulting in the shortening or absence of limbs.
1961 - Dr William McBride (Australia) reported 20% increase in foetal abnormalities and phocomelia in relation with thalidomide use, later numerous reports from other countries (more than 4000 cases) 1962 - USA Kefauver-Harris amendment to the law (requirement to prove safety and efficacy before

issuing MA) 1963 resolution WHA 16.36 reaffirmed the need for early action in regard to adverse drug reactions1964 UK started "yellow cards" system1965
1968: World Health Organization Pilot Project started to pool adverse drug reactions from multiple countries
1997: ICH E2B adopted Electronic reporting standard agreed worldwide1999: Revised Med Watch, draft MedDRA risk issues Introduction of risk management1999: Institute of Medicine - report on errors and concepts
2001: Post marketing safety reporting guidelines - FDA Guidance on how to report adverse events in post marketing phase
2002: PDUFA III - Prescription Drug User Fees Acts allowed FDA to charge fees Allowed FDA to monitor risk post approval, requires companies to monitor risks 2 yrs post approval2003: The "Tome"- 94 pages of proposed rules on adverse event reporting Pre-marketing section finalised in 2010
2004: Draft risk management guidelines
2005: Final risk management guidelines- Specifies how to perform signal detection, risk assessment and risk mitigation 2007: FDA Amendment Act
2008: Volume 9A in EU
2010: New IND Reporting Rule
2010: European PV legislation passed
2011: Volume 10 (Eudravigilance)- Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3'), (2011/C 172/01)
2012: European PV legislation effective (UK SI2012 No 1916)
2014: MHRA Good Pharmacovigilance Practice for Medicines (Dec 14)



- ***The Single Generation Process***

Signals may be generated through four different methods: spontaneous reporting, published case reports, cohort studies and post-marketing clinical trials.
Spontaneous reporting
Recording and reporting clinical observations of a suspected ADR with a marketed drug is known as spontaneous or voluntary reporting. The national system in the UK is the 'yellow card' scheme where doctors, dentists, and recently, hospital pharmacists are encouraged to report all suspected reactions to new medicines and serious suspected reactions to established medicines. Pharmaceutical companies also collect and collate such reports with their licensed products [8]. Reports to companies often come initially as a question from a prescribing physician or pharmacist to Medical Information or a sales representative about whether a product could be the cause of a patient's problem. After providing such information,
Pharmacovigilance staff will seek details of the case to add to the database of reports, this relies on the goodwill and continued interest of reporters. Companies must report suspected ADRs to the MCA and other authorities; some authorities, including MCA

- ***Published case reports***

Case reports of suspected ADRs in medical journals is an established way of alerting others to possible drug hazards. However, it has limitations as only a very small proportion of cases can be published, reports are sometimes poorly documented, publication depends on editorial selection and there is often considerable delay between occurrence and publication. Companies and some regulatory authorities actively monitor the published literature for such reports. This will involve screening key journals where ADRs are described, monitoring publications such as 'Reactions Weekly' (ADIS International)

- ***Cohort studies***

May set up or sponsor prospective, non-interventional cohort type studies either to answer safety questions raised after marketing or as a general hypothesis generating and testing tool to be used as need arises. In the past, company sponsored studies were considered poor at detecting new safety issues mainly because of slow recruitment and lack of control groups [9]. Since 1994 such studies in the UK have been subject to the SAMM (Safety Assessment of Marketed Medicines) guidelines [10] which have ensured a closer dialogue between companies and the MCA. Generally, cohort studies are ineffective as tools for signal generation, mainly because of limitations in size, also data from such studies are subject to the 'signal vs noise' problem in the same way as spontaneous reports.

- ***Post-marketing clinical trials***

Large randomized clinical trials with wide entry criteria (similar to SPC indications) can be valuable in assessing the safety of marketed products as well as confirming efficacy. Because patients are randomised to different treatments they do not have some of the problems inherent in cohort studies, for instance whether the control group is truly comparable. Companies can choose to set up or sponsor such studies to address particular safety issues. To make them sufficiently large to provide more information than the trials performed for product registration purposes may make them prohibitively expensive, hence a simple protocol and study plan with limited observations is desirable.

- ***The hypothesis testing process***

A typical situation in company pharmacovigilance is that a small number of reports have been received, showing that the patients have developed a serious medical condition, e.g. liver function disturbance, convulsions or blood dyscrasia, while receiving a particular product. As much detail as possible on the cases must be obtained and any new cases followed-up rigorously but the hypothesis must be raised that this condition has been caused by the drug, i.e. represents an ADR. For analysis of this question, a number of approaches can be taken, the most common being to use the spontaneous reporting data in a variety of ways.

- ***Using spontaneous reporting data for hypothesis testing***

It is commonplace in clinical practice to make decisions and take actions based on assessment of causality between an event and a certain drug in individual cases. General Pharmacovigilance experience however, is that determination of causality in individual cases has a high degree of uncertainty. Attempts to develop the methodology for causality assessment, e.g. by using a Bayesian approach have yielded interesting results [11] but has so far had little impact. Some exceptions to this uncertainty exist, however, for instance the situation of positive challenge, i.e. that symptoms and objective findings, having disappeared following discontinuation of the treatment, reoccur on renewed exposure. The other situation is when the adverse event in several patients shows a very consistent pattern both in symptomatology and in relation to the duration of treatment before symptoms, e.g. zimeldine and Guillain-Barre syndrome

- ***Epidemiological studies***

During the last decade pharmacoepidemiology, the study of the use and effects of drugs in large populations [13], has emerged as a developing discipline and has made important contributions to our understanding of drug safety. A good example of this is the confirmation and quantification of the relation between NSAID treatment and gastrointestinal ulceration and bleeding [14]. Expertise in pharmacoepidemiology is now a must for any research based pharmaceutical company and there has been a substantial growth of know-how in many over the past few years. In addition, many companies have established research collaborations with academic institutions in pharmacoepidemiology.

- ***ICSR processing of clinical trial casae:***

Clinical trials and pharmacovigilance are parallel processes, whenever any adverse event reported from the patient in trial it will be sent to pharmacovigilance team. Let us see in detail processing of how events experienced in trails gets submitted to regulatory authority.

- ***Who share information about adverse event to sponsor/pharmaceutical Company?***

The investigators in trials are responsible to report all serious adverse events immediately to the sponsor except for those that the protocol or investigator's brochure identifies as not requiring immediate reporting. In cases where reporting is not required immediately, the investigator shall report within the appropriate time frame, taking account of the specificities of the trial and of the serious dverse event, as well as possible guidance in the protocol or the IB.

Non-serious adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations shall be reported to the sponsor according to the reporting requirements and within the time periods specified in the protocol.

- ***Processing and submission of case:***

Sponsor receive the reports it will be sent to case receipt team of pharmacovigilance. Case receipt team and triage team perform primary analysis of the received report to ensure all the required information received or not. If any information is missing then follow up will be sent immediately. Case validity check will be done and primary analysis of seriousness, causality and listedness will be assessed and case sent to global Team for future processing and submission of report

- ***Seriousness:***

Judgement as to whether the event is serious is usually made by the reporting investigator

- ***Causality:***

The assessment of whether there is a reasonable possibility of a causal relationship is usually made by the investigator. In the absence of information on causality from the reporting investigator, the sponsor should consult the reporting investigator and encourage him to express an opinion on this aspect. The causality assessment given by the investigator should not be downgraded by the sponsor.

Expectedness: Assessment of expectedness is usually done by the sponsor. The expectedness assessment will be performed against the Reference Safety Information (RSI) for each IMP to which the event is suspected to be related. If the SAR is considered expected, the treatment allocation will not need to be revealed and the report will simply be filed as a serious adverse reaction until such a time as the treatment allocation for all participants will be revealed. All assessments will be documented on the relevant SAE form.

- ***Post marketing vaccine vigilance***

Like drug pharmacovigilance, vaccine pharmacovigilance aims to detect adverse events early to trigger accurate risk assessment and appropriate response (risk-management) to the problem. This ensures the minimization of negative effects to individuals. Another goal of vaccine pharmacovigilance is to lessen the potential negative impact on immunization programmes.Vaccines, like other pharmaceutical products, undergo extensive testing and review for safety, immunogenicity, and efficacy in the laboratory, in animals, and in three phase's ofclinical trials in human subjects before marketing. Monitoring adverse vaccine reactions is a major safety component of pre-marketing clinical trials.

Why post marketing vaccine vigilance is important?

Post-marketing surveillance of vaccine safety is critical. The conditions and reasons for safety monitoring change following licensure and introduction of a new vaccine. Vaccines are now in use in the general population and recipients are no longer monitored in clinical trial with narrow inclusion/exclusion criteria. Subpopulations commonly excluded in clinical trials (e.g. those with underlying medical conditions, preterm infants) get vaccinated. Large numbers of people are being vaccinated, for example, entire birth cohorts receive infant vaccines. Other factors that can lead to AEFIs, such as incorrect administration practices, need to be monitored for safety.

- ***Medical devices vigilance:***

All regulated countries have distinctly defined medical devices, but Global Harmonization Task Force (GHTF) defined a medical device as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article, which is thereby intended to be used by the manufacturer for human beings for one or more of the specific purposes of:

1. Diagnosis, prevention, monitoring, treatment, or alleviation of disease or compensation for an injury.
2. Investigation, replacement, modification, or support of the anatomy or of a physiological process
3. Supporting or sustaining life
4. Control of conception
5. Disinfection of medical devices
6. Providing information for medical purposes by means of in vitro examination (such as reagents, calibrators, sample collection kits, control materials, and related instruments) of specimens derived from the human body andwhich does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means. Because these devices vary widely in type and are highly essential for patients' care, their manufacture, distribution, and sale must be regulated to ensure their quality, safety, and efficacy. Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling.

- ***Cosmotovigilance:***

Cosmetovigilance is a new concept of safety monitoring of cosmetic products which refers to the post marketing surveillance of any health related undesirable effects possibly due to the use of cosmetic products. The purpose of Cosmetovigilance is to collect, analyse and assess the adverse reactions occurring in consumers to identify any potential health risks, thus guaranteeing a further strengthened safety for consumers. Cosmetovigilance also allows to control or rule out potentially hazardous ingredients that may be present in cosmetic products.Prior to July 2013, the safety of cosmetic products was not reviewed or approved by national regulatory authorities. Since then, new legislation has compelled the cosmetics industry to provide data on products and ingredients before they can be marketed.

- ***Pharmacovigilance of health supplements***

Supplements are substances to add nutrients to diet or to lower risk of health problems, like osteoporosis or arthritis. They come in the form of pills, capsules, powders, gel tabs, extracts, or liquids. They might contain vitamins, minerals, fiber, amino acids, herbs or other plants, or enzymes. Sometimes, the ingredients in dietary supplements are added to foods, including drinks. A doctor's prescription is not needed to buy dietary supplements. Are these supplements safe? Supplements could be harmful, there is no available safety data for them. The regulatory authorities does not have authority over dietary supplements in the same way it does prescription medicines. Few supplements might contain ingredients which can cause harm. It is better to stay away from those unnecessary supplements. If you are thinking about using dietary supplements consider below points before using them;

- Find out as much as you can about any dietary supplement you might take. Know all the ingredients in the list and read scientific articles to confirm safety of each ingredient.
- Just because something is said to be "natural" doesn't mean it is safe or good for you. It could have side effects. It might make a medicine your doctor prescribed for you either weaker or stronger. It could also be harmful to you if you have certain medical conditions.

Worldwide Soilders of Pharmacovigilance

A complex and vital relationship exists between wide ranges of partners in the practice of drug safety monitoring. These partners must jointly anticipate, understand and respond to the continually increasing demands and expectations of the public, health administrators, policy officials, politicians and health professionals

The Quality Assurance and Safety: The team is a part of the Department of Essential Drugs and Medicines Policy, within the WHO Health Technology and Pharmaceuticals cluster. The purpose of the department is to help save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people, particularly the poor and disadvantaged, medicines are unavailable, unaffordable, unsafe or improperly used.

The Uppsala Monitoring Centre: The principal function of the Uppsala Monitoring Centre is to manage the international database of ADR reports received from National Centers.[8] The UMC has established standardized reporting by all National Centers and has facilitated communication between countries to promote rapid identification of signals.

The National Pharmacovigilance Centers: National Centers have played a significant role in increasing public awareness of drug safety. This development is partly attributable to the fact that many national and regional centers are housed within hospitals, medical schools or poison and drug information centers, rather than within the confines of a drug regulatory authority. Major centers in developed countries have established active surveillance programmes using record linkage and prescription event monitoring systems.

Hospitals and Academia: A number of medical institutions have developed adverse reaction and medication error close watch systems in their clinics, wards and emergency rooms. Case-control studies and other pharmacoepidemiological methods have increasingly been used to estimate the harm associated with medicines once they have been marketed. Academic centers of pharmacology and pharmacy have played an important role through teaching, training, research, policy development, clinical research, ethics committees (institutional review boards) and the clinical services they provide.[11–13]

Health Professionals: Originally physicians were the only professionals invited to report as judging whether disease or medicine causes a certain symptom by exercising the skill of differential diagnosis. Today, different categories of health professionals will observe different kinds of drug related problems.

Patients: Only a patient knows the actual benefit and harm of a medicine taken. Direct patient participation in the reporting of drug related problems will increase the efficiency of the pharmacovigilance system and compensate for some of the shortcomings of systems based on reports from health professionals only.

National Pharmacological Center

At present, post – marketing survillence of medicines is mainly coordinated by National Pharmacovigilance Centres. The Central Drugs Standard Control Organization (CDSCO) has initiated a country-wide Pharmacovigilance programme under the aegis of DGHS, Ministry of Health and Family Welfare Government of India.

The programme is coordinated by the National Pharmacovigilance Centre at the Central Drugs Standard Control Organization (CDSCO). The National Centre is operating under the supervision of the National Pharmacovigilance Advisory Committee to recommend procedures and guidelines for regulatory interventions. National Pharmacovigilance Programme The National Pharmacovigilance Programme was officially inaugurated by the Honorable Health Minister Dr. Anbumani Ramadoss on 23 November, 2004 at New Delhi. The National Pharmacovigilance Programme for India, sponsored by the World Health Organization (WHO) and funded by the World Bank, became fully operational in January 2005.9The Programme aims to foster the culture of adverse drug reactions notification in its first year of operation and subsequently aims to generate broad based Adverse drug reactions data on the Indian population and share the information with global health-care community through WHO-UMC.The nationwide programme, sponsored and coordinated by the country's central drug regulatory agency – Central Drugs Standard Control Organization (CDSCO) – to establish and manage a data base of Adverse Drug Reactions (ADR) for making informed regulatory decisions regarding marketing authorization of drugs in India for ensuring safety of drugs. Under the program 26 peripheral centers, 5 Regional Centers and 2 Zonal Centers were established. The Peripheral centers will record the Adverse Events (AE) and send to the Regional Centers. They in turn collate and scrutinize the data received from the Peripheral Centers and submit to the Zonal Centers. The Zonal Centers will analyze the data and submit consolidated information to the National Pharmacovigilance Centre. The Zonal Centre will also provide training, general support and coordinate the functioning of the Regional Center.

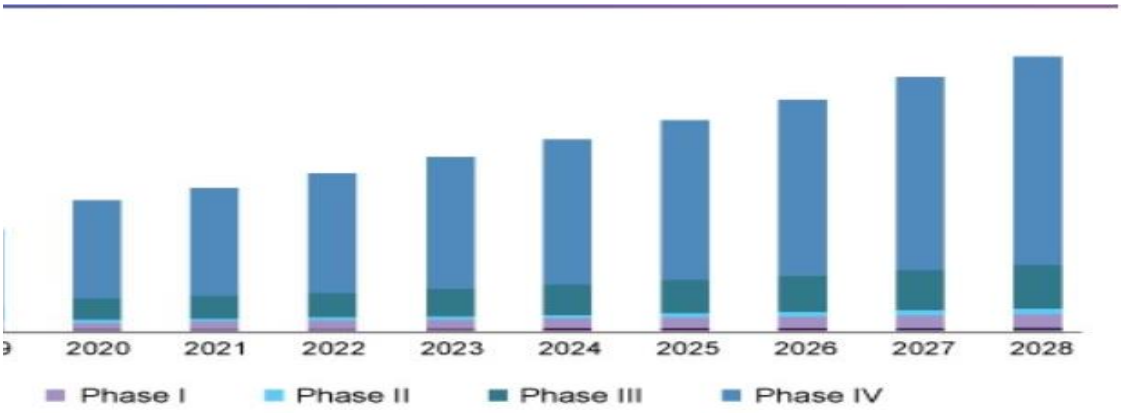
- Peripheral Pharmacovigilance Centres Primary pharmacovigilance centers. Relatively smaller medical institutions including individual medical practitioners' clinics, private hospitals, nursing homes, pharmacies etc. First contact adverse drug reaction data collection unit at a health care facility. They would be identified and coordinated by Regional pharmacovigilance centre or Zonal pharmacovigilance centre in consultation with Central Drugs Standard Control Organization (CDSCO).
- Regional Pharmacovigilance Centers (RPCs) Secondary pharmacovigilance centers. Relatively larger healthcare facilities attached with medical colleges. They would act as second level centers in the administrative structure of the NPPI. They will function as first contact Adverse Drug Reactions data collection units also. They would be identified and coordinated by Zonal Pharmacovigilance Centers in consultation with the Central Drugs Standard Control Organization (CDSCO). 10
- Zonal Pharmacovigilance Centre (ZPCs) Tertiary pharmacovigilance centers. Large healthcare facilities attached with medical colleges in metro cities identified by the Central Drugs Standard Control Organization (CDSCO) for the purpose. They would act as third level centers in the administrative structure of the NPPI. They will function as first contact adverse drug effect data collection units also.

Various Indian regulatory agencies

Agencies
Roles of various Regulatory Agencies
Drug Controller General of India (DCGI): Implementation of the National Pharmacovigilance
Central Drugs Standard Control Organization (CDSCO): Operate under the supervision of the National Pharmacovigilance Advisory Committee to recommend.
Department of Biotechnology (DBT) Provides product evaluation and validation through support for limited and large-scale field trials for agriculture products and clinical trials for health care products.
Ministry of Environment & Forests (MOEF) An autonomous body for the setting of standards for drugs, pharmaceuticals, and healthcare devices and technologies in India.
National Pharmacovigilance Advisory (NPAC) Collates, analyses, and archives adverse drug Committee reaction data for creating a healthy environment for the regulatory authorities to analyze the drug to be marketed in India.
Indian Council of Medical Research (ICMR) Brought out the 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' in 1980 and revised these guidelines in 2000 as the 'Ethical Guidelines for Biomedical Research on Human Subjects.
Ministry of Health and Family Welfare (MHFW) An autonomous body for the setting of standards for drugs, pharmaceuticals, and healthcare devices and technologies in Indi

Pharmacovigilance Market growth and trends

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. The focus of pharmacovigilance is on ADR (adverse drug reactions) and drug toxicity. The pharmacovigilance market comprises all types of adverse events reporting conducted during clinical trials in hospitals, pharmacies, and other healthcare sectors.



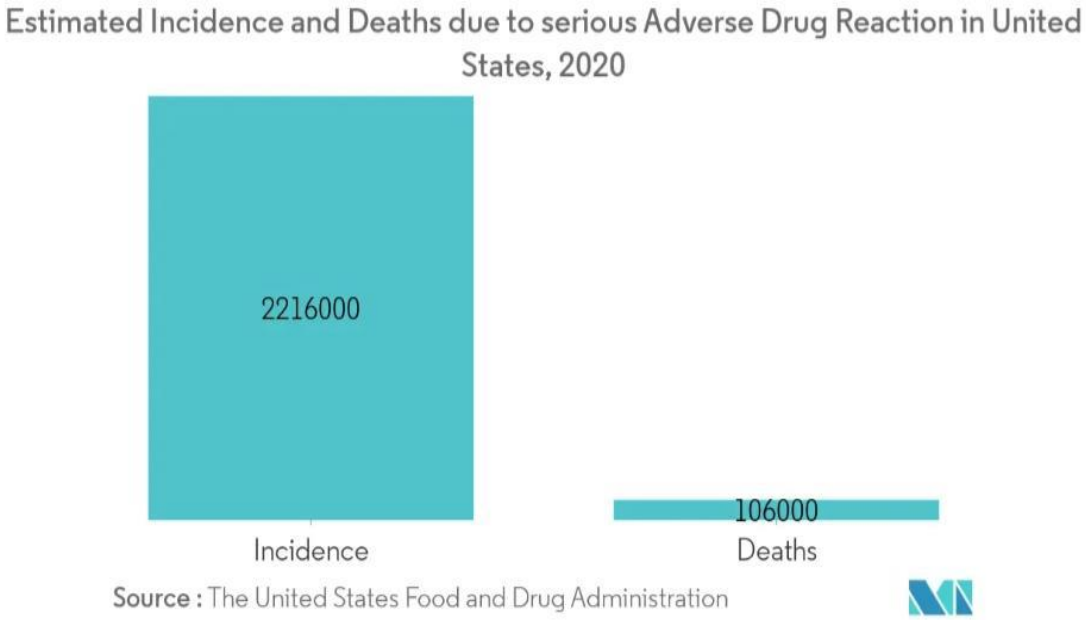
Fig, 1: Market growth and trends

The market is segmented by clinical trial phase (preclinical, Phase I, Phase II, Phase III, and Phase IV), service provider (in-house and contract outsourcing), type of reporting (spontaneous reporting, intensified ADR reporting, targeted spontaneous reporting, cohort event monitoring, and EHR mining), end user (hospitals, pharmaceutical companies, and other end users), and geography (North America, Europe, Asia-Pacific, Middle-East and Africa, and South America). The report offers the value (in USD billion) for the above segments.

- ***Market Overview***

The pharmacovigilance market was valued at approximately USD 5.6 billion in 2020, and it is expected to reach 8.6 billion by 2026, registering a CAGR of nearly 7.54% during the forecast period, 2021-2026 .The evolving threat of COVID-19 infection is adversely affecting communities, industries, businesses, and lives around the world. Medical monitoring and safety reporting are essential as several potential therapies are being used in the treatment of coronavirus-induced infection. Managed by Uppsala Monitoring Centre (UMC). Thus, the rising incidence of adverse drug reactions is anticipated to accelerate the demand for pharmacovigilance services amid pandemics.

The key factors propelling this market are increasing drug consumption and drug development rates, growing incidence rates of adverse drug reactions and drug toxicity, and increasing trend of outsourcing pharmacovigilance services. The increasing incidence of lifestyle-related diseases, such as diabetes, hypertension, and cardiac disorders, as a result of sedentary lifestyles,



In addition, as per the American Cancer Society, in 2020, approximately 1.8 million new cancer cases were reported and approximately 606,520 cancer deaths were reported in the United States. Thus, the increasing burden of a diverse range of diseases among all age groups and globally drives the demand for therapeutic drugs in the treatment of these disorders. With the growing drug consumption, the need for regular monitoring of drugs has also augmented, eventually boosting the pharmacovigilance market.

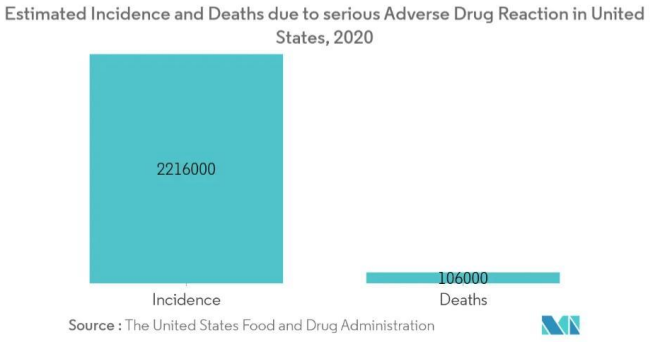
- ***Competitive Landscape***

The pharmacovigilance market is moderately competitive and consists of several major players. In terms of market share, a few of the major players currently dominate the market. Companies like Accenture, IBM Corporation, Wipro, Cognizant, and Capgemini hold substantial market shares in the pharmacovigilance market. The market is competitive in nature, with key participants involved in continuous product developments, collaborations, partnerships, and alliances to augment market penetration...

Study Period:	2018-2026
Base Year:	2020
Fastest Growing Market:	Asia Pacific
Largest Market:	North America
CAGR:	7.54 %

- ***Service Provider Insights***

Outsourcing held the dominant share of 59.24% in 2020 and is expected to witness the fastest growth in the forthcoming years. This is due to the benefits associated with outsourcing such as risk mitigation, resource flexibility, reduction of upfront investments, and lower fixed cost.



Contract outsourcing organizations provide solutions, such as process design Standard Operating Procedure (SOP), PV audits, and other customized services.

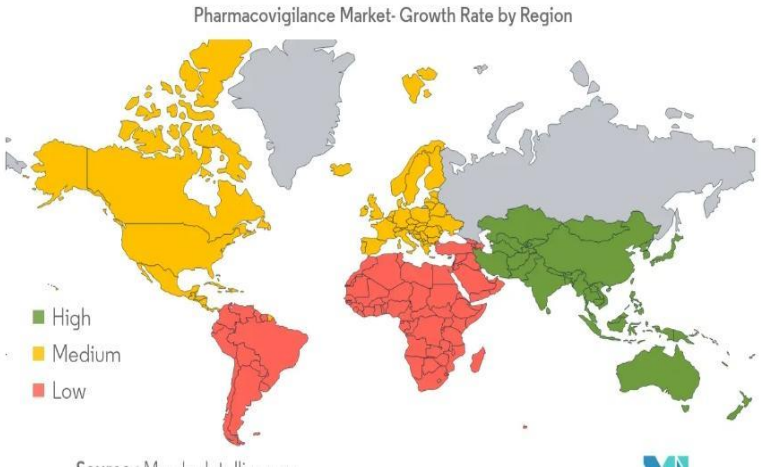


Fig. 2: Pharmacovigilance Market Growth rate by region

The dynamic growth of the contract outsourcing segment can also be attributed to the rapidly emerging CROs providing end-to-end clinical trial solutions, especially in the emerging economies of Asia Pacific, such as India, China, and Japan, enabling resources sharing, cost efficiency, resource flexibility, and expansion of operative capabilities.

- ***Therapeutic Area Insights***

Oncology segment held the largest share of 26.54% as of 2020. Monitoring the safety of cancer drugs is very important due to the associated side effects, which is propelling the demand for pharmacovigilance services. The drugs mostly have intrinsic biological toxicity and narrow therapeutic window, which can lead to serious adverse reactions in the body. The increasing incidence of cancer resulted in accelerated R&D and clinical research. Pharmacovigilance helps in the early detection and spontaneous reporting of adverse drug reactions. Moreover, recent advancements in cancer treatments, such as targeted therapy, have some serious adverse effects and can compromise a patient's quality of life.

- ***End-use Insights***

In 2020, pharmaceuticals held the largest share of 42.63% in terms of revenue. Outsourcing the pharmacovigilance process is practiced by pharma companies to avoid high upfront investments and fixed overhead costs, increase resource flexibility, and secure additional capacity. Outsourcing pharmacovigilance proves to be a cost-effective endeavour for small and medium-sized companiesFi

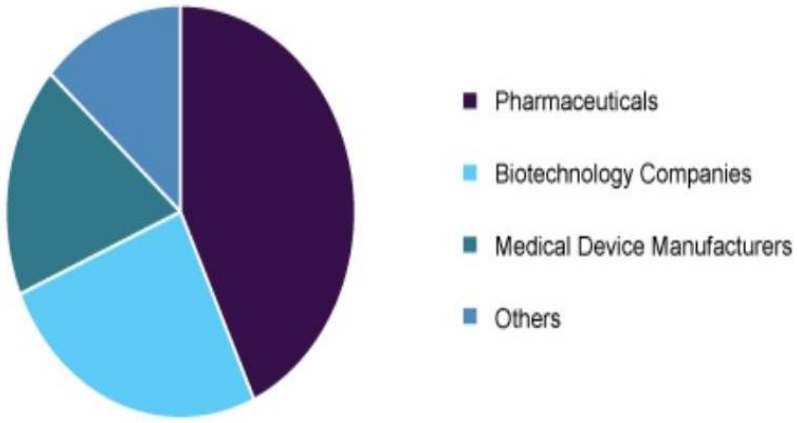
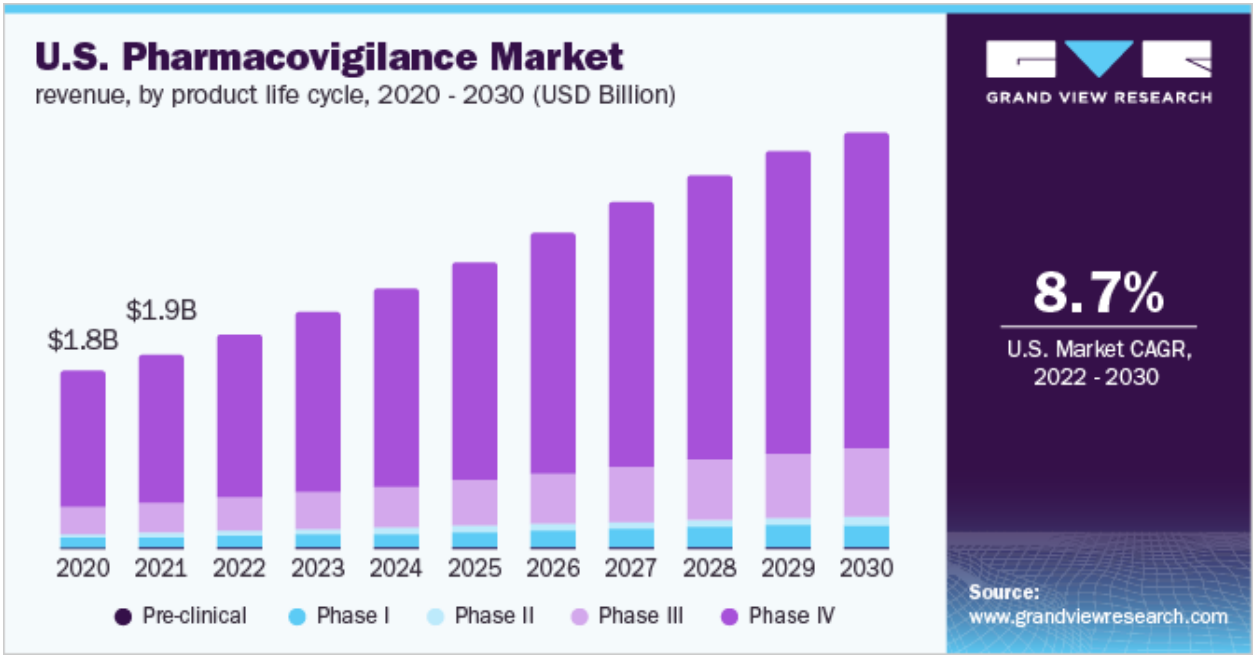


Fig. Pharmacovigilance Market growth

Effective technology companies segment is anticipated to witness lucrative growth in the forthcoming years owing to increasing new product development activities in this sector. In recent years, drugs are being developed and consumed at increasingly high rates.

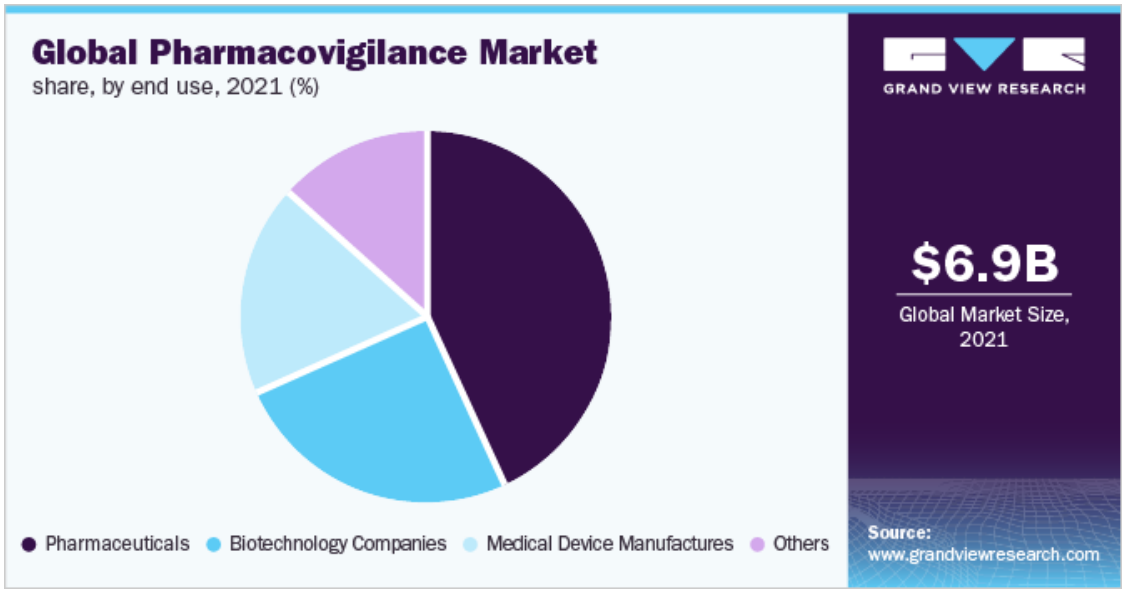
Pharmacovigilance Global Market Overview

The global pharmacovigilance market size was valued at USD 6.97 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 10.5% from 2022 to 2030. An increase in the prevalence of chronic diseases such as oncological diseases, diabetes, and cardiovascular and respiratory disorders has led to an increase in drug consumption worldwide. Therefore, the demand for new drug development via extensive clinical trials has increased. Pharmacovigilance (PV) is the inevitable part of drug discovery and development procedures. The increasing incidence of Adverse Drug Reactions (ADRs) is expected to accelerate the demand for PV services.



In 2021, pharmaceuticals held the largest revenue share of over 40.0% in terms of revenue. Outsourcing the pharmacovigilance process is practiced by pharma companies to avoid high upfront investments and fixed overhead costs, increase resource flexibility, and secure additional capacity. Outsourcing pharmacovigilance proves to be a cost-effective endeavor for small and medium-sized companies.

The biotechnology segment is anticipated to witness lucrative growth in the forthcoming years owing to increasing new product development activities in this sector. In recent years, drugs are being developed and consumed at increasingly high rates. The use of drugs over longer periods by a large population can lead to adverse effects not seen in clinical trials. For instance, Vioxx (an osteoarthritic/ acute pain medication) and Avandia (an anti-diabetic) were marketed for some time before a pattern of safety problems was detected with their use. The growing need for medical information by the regulatory authorities is also anticipated to fuel the growth of this segment.



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