



Overview of Biosimilar in Pharmacovigilance

¹Pratiksha Vishwas Kadav, ²Aishwarya Ramchandra Bhandare, ³Dr. Atish B. Velhal and ⁴Dr. Prakash Dilip Jadhav

¹Department of Regulatory Affairs, YSPM¹, Yashoda Technical Campus, Satara

²Associate Professor, Department of Regulatory Affairs, YSPM's, Yashoda Technical Campus,

³Professor at YSPM's, Faculty of Pharmacy, Yashoda Technical Campus, Satara- 415011

⁴Professor, Department of Pharmaceutics, Satara Yashoda Technical Campus, Faculty of Pharmacy, Wadhe, Satara-415011

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ABSTRACT:

The way we treat cancer patients has changed a lot over the few decades. This is because we now have biologic therapies, which're medicines that have helped cancer patients a lot. However these biologic therapies are very expensive to make which means that many cancer patients cannot afford them. Now that the patents for many of these biologic drugs have expired we have something called biosimilars. Biosimilars are helping to make cancer treatment more affordable for cancer patients. Biosimilars are made to be very similar to the drugs they have the same molecular structure and work in the same way and they are just as safe as the biologic drugs. Even though biosimilars are very similar to the biologic drugs we still need to keep an eye on how safe they're when cancer patients use them. This is where pharmacovigilance systems come in they help us find out if there are any problems with these medicines after they have been approved. This study looked at the safety of monoclonal antibodies which're biologic therapies used to treat cancer. We compared them to the drugs and we used data from the EudraVigilance database, which covered two years from 1 January 2021 to 31 December 2022.

We found that most of the problems reported with biosimilars were not serious they were the kinds of problems that we see with the biologic drugs. So our study shows that biosimilars are just as safe as the biologic drugs, which means that biosimilars can be an alternative to the biologic drugs. They can help cancer patients get the treatment they need at a cost.

Introduction

Biological medicines have really changed the way we treat diseases. They offer targeted and effective treatment options for conditions like cancer, autoimmune disorders, inflammatory bowel disease, diabetes and rheumatologic conditions. These medicines, often called biologics come from living things. Are made using advanced technology. Over the twenty years biologics have become some of the most valuable medicines worldwide.. They are very expensive to develop and make, which limits access for patients especially in developing countries where healthcare resources and

insurance are limited. Now that patents and data exclusivity periods for original biologics have expired biosimilars have emerged. Biosimilars are similar to approved biological medicines and are designed to provide similar safety, quality and effectiveness at a lower cost. As biosimilars become widely available making sure they are safe through strong monitoring systems has become very important for regulators and public health. Biological medicines are really making a difference. Biosimilars are helping to make them more accessible. The use of biologics and biosimilars is. Their impact, on healthcare is being closely watched.



Table 1. Definitions of Biosimilars According to Major International Regulatory Authorities

Regulatory Authority	Definition	Additional Key Points
European Medicines Agency (EMA)	A biosimilar is a biological medicinal product that shows a high degree of similarity to an already authorised biological medicine, known as the reference product. It has been approved by showing evidence and comparing quality, safety, and clinical performance.	<ul style="list-style-type: none"> • In-depth comparison studies are mandatory, including laboratory tests, pre-clinical studies, and clinical trials. • No differences should be seen compared to the original drugs. • Pharmacovigilance and safety are monitored, and risk management plans are required.
U.S. Food and Drugs Administration(FDA)	A biosimilar is a biological medicine that is made by very similar to an already approved original medicines by the FDA. It should be shown number of importance in difference in terms of safety, quality and effectiveness and it should be work in same way as the original medicine in patients.	<ul style="list-style-type: none"> • It must go through strictly rigorous scientific tests to prove its similar and original medicine. • It Can be “interchangeable” status if additional conditions are required. • It is Required to continuously monitored after even after it is sold in the market
World Health Organisation (WHO)	A Biosimilar is aslo Known as similar biotherapeutic product, it is a biological medicine that is made to be very similar to an already approved biological medicines. It should have to comparable quality, safety, and effectiveness in treating patients.	<ul style="list-style-type: none"> • It Provide you global guidelines and support and different country can follow similar rules • It Emphasises stepwise checking biosimilar step by step to make they are similar to the original biologic medicine. • It helps to affordable biological treatments and available to patients around the world.
Additional General Considerations	Biosimilar are not exactly same but they are original medicines because (unlike generics for small-molecule drugs) due to the complex nature of biological manufacturing. This make it difficult to create an extra copy unlike generic drugs which are simple chemicals. However, biosimilars must show that they work just	<ul style="list-style-type: none"> • Biosimilar are developed after patent termination of the original biological expires They Contribute to reduce the cost and improved patients access of these medicines



	<p>as well and are just as safe as the original biologic medicine in patients.</p>	<ul style="list-style-type: none"> It is very important to make sure that Manufacturing Regularity Immune response are critical components doe’s not case unwanted immune reactions in the body.
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Table 2 Comparison of Generic, Biosimilar, and innovator products

Process	Biologic	Biosimilar	Generic
Manufacturing	The Production process is very sensitive because of using biological process even small changes in expensive and specialized production facilities and expensive equipment are required.	The manufacturing process is very sensitive and so small changes can affect the medicine. Because of this, special equipment and facilitates are needed, which makes production expensive.	The manufacturing process is made of synthesis so small changes during production usually do not affect the medicine much.
Clinical	Even after the medicine is approved, its safety is continuously monitored. Medicines need many clinical trials, including Phase I, Phase II, and Phase III studies, to check their safety and effectiveness reports.	After the medicine are approved it is continuously monitored for their safety and regularly safety report are submitted to authorities.	Because the process is simpler, the approval time is shorter and the medicine can enter the market faster.
Development	The medicine must go through several clinical trial phases (Phase I, Phase II, and Phase III) to check its safety and effectiveness.	The medicine is approved and its go through three stages of clinical trials (Phase I, Phase II, and Phase III) to make sure it is safe and works well.	Short timeline for approval
regulation	The medicine must show that it is very similar (comparable) to the original biologic medicine in terms of safety, quality, and effectiveness.	The medicine must prove that it is very similar to the original biologic medicine in safety, quality, and effectiveness.	The medicine must show bioequivalence, which means it works in the same way as the original medicine in the body.
Production Sensitivity	Very sensitive to small changes in production.	Also sensitive to production changes.	Less sensitive to production changes.



Substitution	Cannot be automatically substituted with another product.	Usually not automatically substituted with the original biologic medicine.	Can be automatically substituted with the brand medicine in pharmacies.
Cost (Extra Point)	Very expensive.	Cheaper than biologics but still costly.	Much cheaper than brand drugs.
Examples(Extra Point)	Insulin, Monoclonal antibodies.	Biosimilar insulin or biosimilar antibody drugs.	Paracetamol, Ibuprofen generics.

Increasing Global Use of Biosimilars

- The Biosimilars are used globally and are increasing rapidly due to their cost – effectiveness and comparability of therapeutic efficacy reference biologic products. Adoption of biosimilars is being promoted to improve their patient access to biological therapies and reduce healthcare costs. Guiding authorities to develop their clear approval pathways, which has further supported their growth in the pharmaceutical market.
- In the addition of the expiration of patents for May biological medicines has created opportunities for biosimilar development. As a result, pharmaceutical companies are increasingly investing in biosimilar research and production. The awareness among healthcare professionals and patients has also contributed to the wider acceptance and use of biosimilars worldwide.

Importance of Pharmacovigilance in Biologics

Pharmacovigilance (PV) refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

Pharmacovigilance is particularly important for biologics because:

- Biologics are complex and sensitive to manufacturing variations.
- Minor structural differences may trigger immunogenic reactions.

- Rare adverse events may not be detected during pre-marketing clinical trials.
- Long-term safety data are often limited at the time of approval.

Changes in manufacturing processes, scale-up procedures, or raw materials can influence product consistency. Regulatory authorities such as the EMA and US FDA require continuous monitoring of biologics throughout their lifecycle to ensure ongoing safety, quality, and efficacy.

Why Pharmacovigilance is Especially Critical in Biosimilars?

Pharmacovigilance plays an even more critical role in biosimilars due to the following reasons:

1. Immunogenicity Risk

Even small differences in post-translational modifications or impurities may alter immune responses. Monitoring for anti-drug antibodies and immune-related adverse events is essential.

2. Interchangeability and Switching

Switching between a reference product and its biosimilar may raise concerns about immunogenicity or reduced efficacy. Although current evidence does not demonstrate increased risk, robust post-marketing surveillance is necessary to maintain public confidence.

3. Extrapolation of Indications

Biosimilars may receive approval for multiple indications based on clinical data from one indication.



Pharmacovigilance ensures that safety remains consistent across all approved uses.

4. Traceability and Product Identification

Clear naming, labeling, and batch traceability are crucial to accurately attribute adverse events to specific products.

5. Manufacturing Variability

Since biosimilars use independent manufacturing processes, continuous monitoring is required to detect any impact of process variability on clinical outcomes.

6. Global Market Expansion

As biosimilars are increasingly used in developing countries with evolving regulatory systems, strengthening PV systems becomes essential to ensure patient safety.

Characteristics of Biosimilars

- Biosimilars are biological medicines that are highly similar to an already approved reference (originator) biologic product. Although they are not identical due to the complex nature of biologics, they show no clinically meaningful differences in terms of quality, safety, and efficacy.

- One important characteristic of biosimilars is high similarity in structure and function. They must have the same amino acid sequence as the reference product and demonstrate comparable biological activity. Minor differences may exist in inactive components, but these do not affect clinical performance.
- Another key feature is comparable quality attributes. Biosimilars undergo extensive analytical testing to confirm similarity in physicochemical properties, purity, potency, and stability.
- Safety and efficacy equivalence is also essential. Clinical studies are conducted to demonstrate that the biosimilar works in the same way as the reference product and has no significant differences in therapeutic outcomes.
- Immunogenicity assessment is a critical characteristic. Since biologics can trigger immune responses, biosimilars must be carefully evaluated to ensure they do not cause increased immune reactions compared to the original product.
- They must also follow a strict regulatory approval pathway, involving stepwise comparability exercises including analytical studies, non-clinical studies, and clinical trials.

Difference Between Biosimilar, Reference Biologic & Generic

Feature	Reference Biologic	Biosimilar	Generic
Nature	Original biologic medicine	Highly similar to reference biologic	Exact copy of chemical drug
Source	Made from living cells	Made from living cells	Made by chemical synthesis
Molecular Structure	Large, complex proteins	Similar large, complex proteins	Small, simple molecules
Development	Full research & complete clinical trials	Comparative studies with reference product	Bioequivalence studies only
Approval Pathway	Full regulatory approval	Abbreviated but strict comparability pathway	Abbreviated generic approval



Identical to Original?	Original product	Not identical, but highly similar	Yes, identical
Cost	High	Moderate (lower than originator)	Low

Concept of Pharmacovigilance (PV)

Pharmacovigilance is the science and set of activities used to detect and understanding, prevent adverse side effects or other problem related to drugs. It plays an important role in ensuring the safety, effective, and of good quality of medicines throughout their life cycle, from clinical trials to their development to post-marketing use.

Pharmacovigilance aims to identify suspected adverse drug reactions (ADRs) and monitor the benefit-risk of medications to promote patient safety. Collecting, analyzing, and disseminating safety data from doctors, health care providers, patients, and pharmaceutical companies are also components of pharmacovigilance. Pharmacovigilance assists regulatory authorities and healthcare systems in determining actions to take (i.e., updating safety information, restricting drug usage, or withdrawing from the market) it involves continuing to monitor and assess data on the safety of medications.

Definition of Pharmacovigilance (PV)

According to the World Health Organization (WHO):

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

Objectives of Pharmacovigilance

The main objectives of pharmacovigilance are:

1. Detection of Adverse Drug Reaction (ADRs)

To systematically detect, document, and analyse adverse drug evaluate undesired pharmacological effects associated with medicinal products.

2. Evaluation of Therapeutic Risk-Benefit Ratio

To evaluate the balance between clinical efficacy and potential adverse outcomes of pharmaceutical interventions.

3. Prevention of Drug-Related harm

To implement strategies that include preventive measures that reduce the incidence of medication-related injuries or complications.

A. Monitoring Long – Term Safety

To conduct continuous surveillance of drugs post-marketing to detect delayed or rare adverse effects.

B. Regulatory support and policy Guidance

To provide scientifically robust data to regulatory bodies for updating drug safety guidelines, labelling, and usage recommendations.

Importance of Pharmacovigilance in Biological Products

Pharmacovigilance plays a very important crucial role for safety, efficacy, and quality of biological products because these medicines are made from living cells or organisms. Examples such as vaccines, monoclonal antibodies, and recombinant proteins are complex; they may sometimes cause side effects that are not seen during clinical trials. Pharmacovigilance helps in the early identification and evaluation of adverse drug reactions (ADRs) and other safety-related issues associated with biological medicines. It also supports the continuous assessment of the benefit–risk balance of these products during their widespread use in the population. In addition, pharmacovigilance systems facilitate the collection and analysis of post-marketing safety data, which helps regulatory authorities and healthcare professionals detect potential risks and take appropriate regulatory measures. These measures may include updating safety information, modifying treatment guidelines, or implementing risk-management strategies to ensure the safe and effective use of biological products.

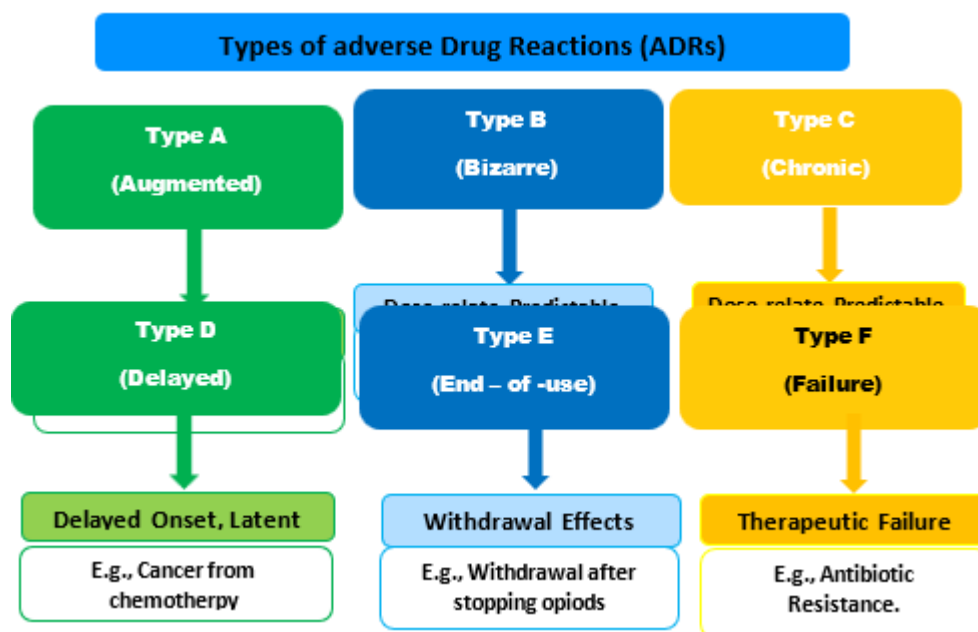
ADR (Adverse Drug Reaction)

Definition of ADR

According to WHO: An ADR is a response to a drug which is noxious and unintended and occurs at doses



normally used in humans for prevention, diagnosis, or treatment.

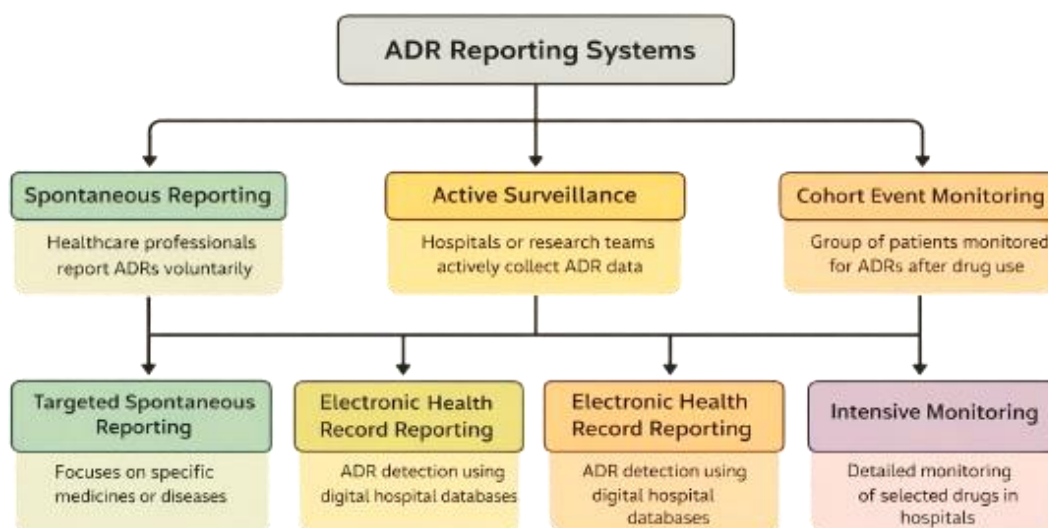


Definition of ADR reporting system

An ADR reporting system is a structured method through which healthcare professionals, patients, and pharmaceutical companies report suspected adverse drug reactions to regulatory authorities.

Types of ADR Reporting Systems

Challenges in Pharmacovigilance of Biosimilars





Underreporting

The identification and prevention of Adverse Drug Reactions is a part of keeping people safe from bad reactions to medicine. Adverse Drug Reactions are a concern. However there are problems that make it hard to do this well. With systems in place to report Adverse Drug Reactions it is still hard to catch every bad reaction. Many countries have systems to report Adverse Drug Reactions. It is still difficult to make sure every bad reaction is written down.

Adverse Drug Reactions are a deal. Various groups that watch out for Adverse Drug Reactions work together in countries to keep an eye on Adverse Drug Reactions. These groups work in countries that do not have a lot of money. The following table shows some examples of systems that report Adverse Drug Reactions and help, with this work.

S r N o.	Reporting system	Cou ntry
1.	Pharmacovigilance Programme of India - (PvPI)	Indi a
2.	National Pharmacovigilance Centre - (NPC)	Nig eria
3.	Health Products Regulatory Authority (SAHPRA) is a mouthful so lets call it South African Health Regulator	Sout h Afri ca
4.	National Agency of Drug and Food Control we just call it BPOM Indonesia.	Indo nesi a
5.	Brazilian Health Regulatory Agency (ANVISA) is a name lets just say Brazils Health Regulator Brazil	Bra zil

Pharmacovigilance Training in LMICs

The thing with pharmacovigilance is that it is really hard to find people who are trained to do this kind of work. This is because not many people have access to the education and training in pharmacovigilance.

Some places do offer courses in pharmacovigilance.. A lot of universities do not teach pharmacovigilance in their classes. So when people finish school and start working in healthcare and pharmaceutical companies they often do not know enough about pharmacovigilance like how to collect data report reactions to drugs and figure out if there are safety problems, with certain drugs.

Funding Constraints

Pharmacovigilance activities in low and middle-income countries depend on outside funding. This funding is not always available causing problems for these programs. In countries with limited resources people working in pharmacovigilance do not get paid as much as those in other healthcare areas. In some places like India pharmacovigilance jobs are often temporary and not permanent.

Many Adverse Drug Reaction Monitoring Centres get financial help. This limits their ability to do outreach programs run awareness campaigns and provide training, for professionals. They also do signal analysis.

Public Engagement

Another big challenge is that patients are not involved enough in reporting drug reactions. In developing countries people often take medicines without proper medical guidance.

If patients are not encouraged to report reactions it can lead to underestimation of safety issues related to medicines. This can also cause delays in spotting warning signs of adverse reactions.

Getting patients to participate and making them aware of reporting reactions can really help improve pharmacovigilance systems and medication safety. Patients reporting drug reactions is key patients are crucial in pharmacovigilance and patient participation, in ADR reporting is vital.

Reporting Form

The way ADR reporting forms are designed and how easy they are to use can really affect how well pharmacovigilance systems work. In some places these forms can be really hard to fill out. They can be hard to find or they are just not set up very well. This makes it so that doctors and nurses and patients do not want to bother filling them out.



Sometimes people do not speak the language as the form. This is especially true in countries where people speak a lot of languages. If the ADR reporting forms are not in the language that people speak at home then a lot of people will have a time reporting when they have a bad reaction, to a drug.

If we make the forms easier to fill out and have them in languages then more people will report bad reactions to drugs. This is because ADR reporting forms will be simpler and people will be able to fill them out in their language. The ADR reporting forms will be better. People will use them more.

Regulation-Related Issues

The rules that are supposed to help with drug safety monitoring are not good enough in a lot of developing countries. Sometimes these rules are not enforced well. When we have rules for reporting bad reactions to drugs they do not always work because the people in charge do not have the resources they need.

Some people did a study. Found out that a lot of big pharmaceutical companies do not do a good job with drug safety monitoring. For example these companies may have offices in India. They do not always follow the rules for reporting bad reactions to drugs. The people who did the study like Moscoe and his colleagues talked to companies that sell drugs in countries.

We need to make the rules for drug safety monitoring and make sure people follow them. This is important for making sure drugs are safe to use in the world. We need to strengthen the systems that are supposed to regulate drug safety monitoring. This will help us improve the way we monitor drug safety, over the world. Drug safety monitoring is very important. We need to do a better job with it.

Future Perspectives for Biosimilars

Biosimilars are expected to play a very important role in the future of healthcare. As many patents of original biologic medicines expire, more pharmaceutical companies are developing biosimilars. This will increase the availability of these medicines and help reduce the cost of treatment for patients. Because biologic drugs are often very expensive, biosimilars can make advanced therapies more affordable and accessible, especially in developing countries.

In the coming years, improvements in biotechnology and manufacturing processes will make the development of biosimilars more efficient and reliable. Regulatory authorities such as global health organizations and national agencies are also continuously updating guidelines to ensure the safety, quality, and effectiveness of biosimilars. These regulatory improvements will help increase confidence among healthcare professionals and patients.

Another important future aspect is the growing acceptance of biosimilars in clinical practice. As more clinical data and real-world evidence become available, doctors and patients will become more comfortable using biosimilars as alternatives to reference biologics. Pharmacovigilance systems will also become stronger to monitor the long-term safety of these products.

Overall, the future of biosimilars looks promising because they have the potential to improve patient access to life-saving treatments, reduce healthcare costs, and promote innovation in the pharmaceutical industry

Conclusion

Biosimilars are a deal in healthcare today. They give us options for expensive biologic medicines without losing any of the good things they do. Biosimilars help people get the treatments they need especially when money is tight.

Biosimilars are not exactly the same as the biologic medicines they are based on. This is because biologic medicines are very complex and hard to make. So we have to keep an eye on biosimilars to make sure they are safe. We need to watch for any problems that might come up after they are approved.

Biosimilars need to be watched all the time to make sure they are safe. This is where pharmacovigilance comes in. It helps us find any unexpected bad reactions to biosimilars. We also need to check if peoples bodies are reacting to biosimilars in a way.. We need to be able to track biosimilars so we know what is happening with them.

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