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Original Article

The Economics Orphan Drugs: Supply Chains, Data Security, and Transparency

Utkarsha Sawant*, Pratiksha Ghodake, Shrushti Shahane, Swapnil Kale, Sneha Kanase

Arihant College of Pharmacy, Ahilyanagar

ABSTRACT

Orphan drugs are those developed to treat rare diseases and are subject to unique economic pressures–small patient populations and high outlays required to produce them.That ensures these drugs are available all the time requires coordination among manufacturers, distributors, and health care providers, and overcoming logistical challenges and disruptions.Visibility and security of data are critical in the orphan drug industry given the significant reliance on patient data for research, research & development clinical trials, and personalization of treatment. This sensitive information should be stored with strong cybersecurity measures and compliance with the privacy laws (GDPR, HIPAA, etc.) in order to keep it safe and maintain people's trust. Also, data sharing among stakeholders, where data is open and safe, invites collaboration that is critical in enhancing drug development, regulatory processes and supply chain management. This overview illustrates the confluence of supply chain, data security and transparency that determine the economics of orphan drugs, showing how we must be creative to ensure orphan drugs are accessible, affordable, and manufactured in the most efficient manner possible.

Keywords: There overview of regulatory incentives,market dynamics,market size, growth trends and economic factors influencing orphan drugs development,pricing strategies and reimbursement challenges,supply chain,challenges in orphan drug development,complexities of manufacturing and distribution,use electric vehicles,partner with local businesses, use GPS tracking and mobile apps, global supply chain disruptions,especially post-COVID-19,big data and AI,adoption of advanced manufacturing techniques,additive manufacturing,role of digital tools in improving supply chain transparency and security,automated data loggers,cost reduction,data security in orphan drug research and development, importance of data orphan drugs development, strategies,need of transparency in pricing, the role of transparency in building trust with patients,healthcare

INTRODUCTION

● Orphan drugs are medicinal products developed specifically to treat diseases which, by definition, affect only a small portion of the population. Many of them are called orphan diseases that are serious, life-threatening and chronic, including cystic fibrosis, Huntington's disease or rare cancers.

● **Economics challenges unique to orphan drugs: -** The development and distribution of orphan drugs present several economic challenges that differentiate them from traditional pharmaceuticals. These challenges stem primarily from the small patient populations they serve and the complexities of developing treatments for rare diseases.

• Scope of the Research analysing the economics of orphan drugs

1) Supply Chains:-

Production and distribution obstacles: - The limited patient populations for rare diseases, often scattered across various locations, create challenges in manufacturing and logistical aspects.

Cost Analysis: -Evaluating production, transportation and storage costs for bottlenecks.

Sustaining: - Securing continued supply while minimising threats of shortages or disruption.

2) Data Security: -

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Patient Privacy: -Protecting sensitive patient data in compliance with regulations such as GDPR and HIPAA.

Industrial Data: -This information is about protecting secret formulas, production processes and clinical trials from hackers.

The Role of Technology: -Analysing blockchain and artificial intelligence tools for data security.

3)Transparency: -

Pricing Models: -Why we are paying so much for drugs, and why nobody seems to know how much they cost.

Regulatory Oversight: -Examining the compliance and reporting regimes in different jurisdictions.

Provide information to patients, regulators, manufacturers and healthcare providers to build trust with stakeholders.

Background on Orphan Drugs

1) Regulatory Framework: -A regulatory framework is a set of rules, regulations, and laws that govern how a sector or industry operates. It is known as a regulatory framework.

India: -Defines orphan drugs as drugs that treat conditions affecting no more than 500,000 people. The Central Drugs Control Standards Organization (CDSCO) can waive the need for local clinical trials, and clinical trial sponsors can request a faster approval process.

United States: -a disease as rare if it affects fewer than 200,000 people. The Orphan Drug Act (ODA) of 1983 incentivizes pharmaceutical companies to invest in orphan drugs.

European Union: -Defines a disease as rare if it affects fewer than 1 in 10,000 people.

2)What Is Orphan Drugs?

Orphan drugs are used to treat, prevent, or diagnose a rare disease or condition.it is also known as orphan drugs.

3)The Criteria for Orphan Designation: -

●A medicine, including vaccines or in vivo diagnostic agents, may qualify for orphan drug designation if it meets all the criteria outlined in regulation 16J of the Therapeutic Goods Regulations 1990.

●Along with the standard orphan designation pathway, there is an additional pathway for medicines in new dosage forms.

●This pathway aims to encourage sponsors to register medicines on the Australian Register of Therapeutic Goods (ARTG) by offering a TGA fee waiver for new dosage forms that would otherwise not be financially viable.

4)Overview of Regulatory Incentives

•**Tax Credits: -**Tax credits can cover up to 50% of research and development costs in the United States.

•**User Fee Waivers: -**The Prescription Drug User Fee is waived for orphan drugs.

•**Market Exclusivity: -**After approval, orphan drugs are granted market exclusivity for up to seven years.

•**Financial Support: -**The Office of Orphan Products Development (OOPD) provides financial assistance to researchers who apply for orphan drug designation.

•**Protocol Guidance: -** Protocol assistance is available to help with the development of orphan drugs.

•**Priority Review Vouchers: -** Vouchers are available for rare paediatric and tropical diseases.

•**Grants: -**Grants are available to support the clinical development of orphan drugs.

Market Dynamics

1) Rising Prevalence of Rare Diseases: -Rare Diseases are becoming more common as diagnostics improve and awareness grows. This increased visibility results in a larger patient pool in need of treatment, which drives up demand for orphan medications.

2) Unmet Medical Needs and Limited Treatment Options: -Many uncommon diseases do not have viable treatments, resulting in a huge unmet medical demand. Orphan medications provide an opportunity to close this gap by encouraging pharmaceutical corporations to engage in research and development.

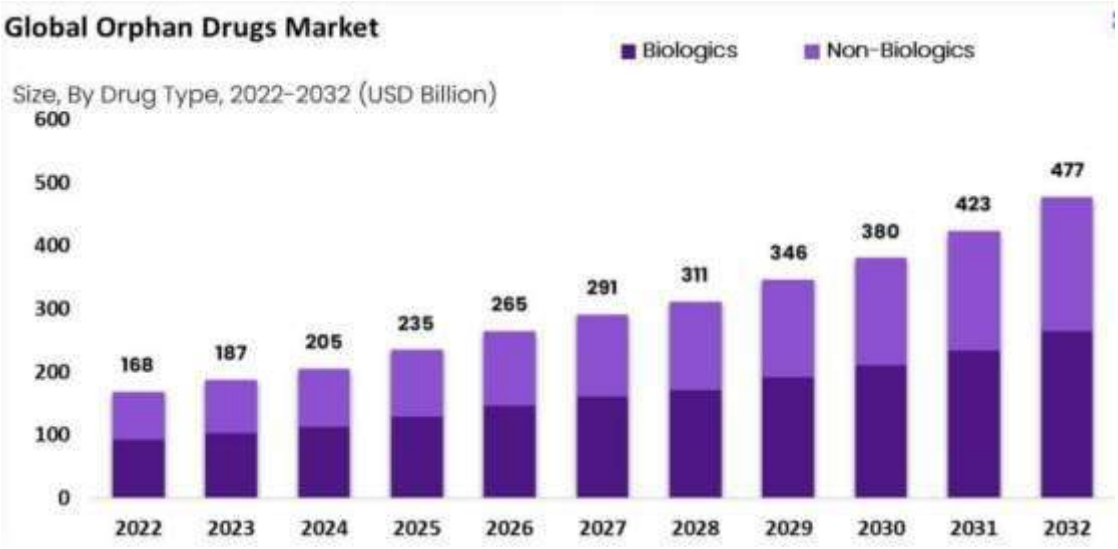
3) Technological advancements and innovation:- Breakthroughs in gene therapy, personalised medicine, and biological drug development are making way for more targeted and effective orphan medications. These breakthroughs have the potential to lead to curative treatments and better patient outcomes, which will drive market expansion even further.

4) Growing Public and Patient Advocacy: -Medical developments and strong patient advocacy groups have contributed to increased awareness of rare diseases. These organisations create public awareness, lobby for government funding, and promote research and development, thus moving the orphan medicine industry ahead.

5) Focus on Orphan Drugs in Pharmaceutical Companies: - Pharmaceutical corporations are allocating more resources to orphan medication development, recognizing the business opportunity and ethical obligation. This not only benefits patients with uncommon diseases,but it also provides firms with the opportunity to earn huge returns on investment.

6) Growing financing Opportunities: - Increased government financing for research grants, as well as public-private partnerships focusing on rare diseases, are making it easier to produce orphan drugs. This financial support enables early-stage research and clinical trials, eventually leading to a broader range of orphan drug choices.

◇ Orphan Drugs Market Overview: - Orphan drugs market size was valued at USD 196.60 billion in 2023 and is projected to grow from USD 219.54 Billion in 2024 to USD 480.27 billion by 2032, exhibiting a compound annual growth rate (CAGR) of 9.08% during the forecast period (2024-2032). The rising prevalence of rare diseases, growing investment. in research and development of orphan drugs.



■ Economic Factors Influencing Orphan Drug and Development: -

Orphan drug incentives have encouraged research into rare diseases with unmet medical needs. Despite smaller patient populations, orphan drugs generate similar revenue to non-orphan drugs. They may also be more profitable due to factors like government. incentives, smaller and faster clinical trials, and higher regulatory approval rates, making rare disease research a valuable biopharma R&D strategy.

◇ Pricing Strategies and Reimbursement Challenges

☆High Cost of Research and Development: -: Developing orphan medications is a significant financial burden. The tiny patient population

necessitates fewer clinical trials, presumably higher expenses per participant, and difficulty recouping investment through sales. This high cost can dissuade pharmaceutical companies from developing new orphan medications.

☆ **Limited Patient Population and Recruitment Challenges: -**The nature of uncommon diseases poses a hurdle in medication development. Small patient populations make it challenging to organise and carry out rigorous clinical trials to collect adequate data on safety and efficacy. Recruiting patients for these trials can be a time-consuming and complex process, further delaying market approval.

☆ **Pricing and Reimbursement Challenges: -** Because of the high development costs and small market size, orphan medications can be extremely expensive. This high cost can make it difficult to get insurance coverage and ensure that patients have access to life-saving medications. Striking a balance between recouping investment and guaranteeing patient affordability is an important but difficult challenge.

☆ **Lack of Long-Term Data on Safety and Efficacy: -** Long-term data on the safety and efficacy of orphan medications are restricted due to the small number of patients engaged in clinical studies. This absence of long-term data may complicate regulatory approval and create worries among healthcare practitioners and patients about the potential hazards and benefits of these treatments.

◇ **Supply Chain, Challenges In Orphan Drug Development**

■ **Complexities of Manufacturing and Distribution**

Raw material supplying or procurement, the production process, and storage and distribution systems for finished products

1. **Global Challenges**

Even small businesses must deal with suppliers, logistics and regulations from around the world

2. **Product complexity**

The number and nature of its components and how they interact

3. **Manufacturing processes**

Some manufacturing processes, like batch processing can be very difficult

4. **Design complexity**

Design complexity is determined by the volume and area ratios of a part design

5. **Factors affecting manufacturing process selection**

The quantity of the product, the cost of materials and equipment, the time required for processing.

■ **Overview of Manufacturing Challenges**

☆**Capacity Planning Challenges: -** Capacity planning is the process of determining the production capacity needed by an organisation to meet changing demands for its products. It involves forecasting demand, analysing capacity, and making decisions about investments in equipment, facilities, and personnel.

☆**Quality Control Challenges: -** Quality control is the process of ensuring that products and services meet certain standards of quality. Quality control systems are designed to detect defects and prevent them from being released into the marketplace.

☆**Cost Reduction Challenges: -** Cost reduction is the process of identifying and eliminating unnecessary costs in order to increase profits. Cost reduction initiatives can include streamlining production processes, reducing waste, and outsourcing certain activities.

☆**Supply Chain Management Challenges: -** Supply chain management is the process of managing and coordinating the flow of materials and information between suppliers, manufacturers, distributors, and customers. It includes activities such as inventory management, order fulfilment, and transportation.

☆**Automation Challenges: -** Automation is the use of technology to automate processes and reduce

labour costs. Automation can involve complex systems, such as robotics, or simpler processes, such as automated production lines.

■ Logistics and Distribution Challenges Due To Limited Demand And Specific Storage And Transportation Needs

● Transportation and distribution are important parts of the economy, but they face many challenges some strategies and technologies that can help businesses improve their efficiency: -

1)Use Electric Vehicles: - Electric vehicles can reduce a business's carbon footprint and help with traffic and parking issues.

2)Use Drones: - Drones can deliver small packages quickly and efficiently over short distances.

3)Partner with local businesses: - Businesses can work with local shops and stores to offer package pickup locations.

4)Use smart lockers: - Smart lockers are automated systems that allow customers to pick up packages at any time.

5)Use GPS tracking and mobile apps: - These technologies can provide customers and logistics managers with real-time delivery visibility. It can lead to delays in product delivery, increased costs, and customer dissatisfaction. The entire process of planning, implementing and controlling the efficient flow and storage of goods, services, and information from the point of origin to the final customer.

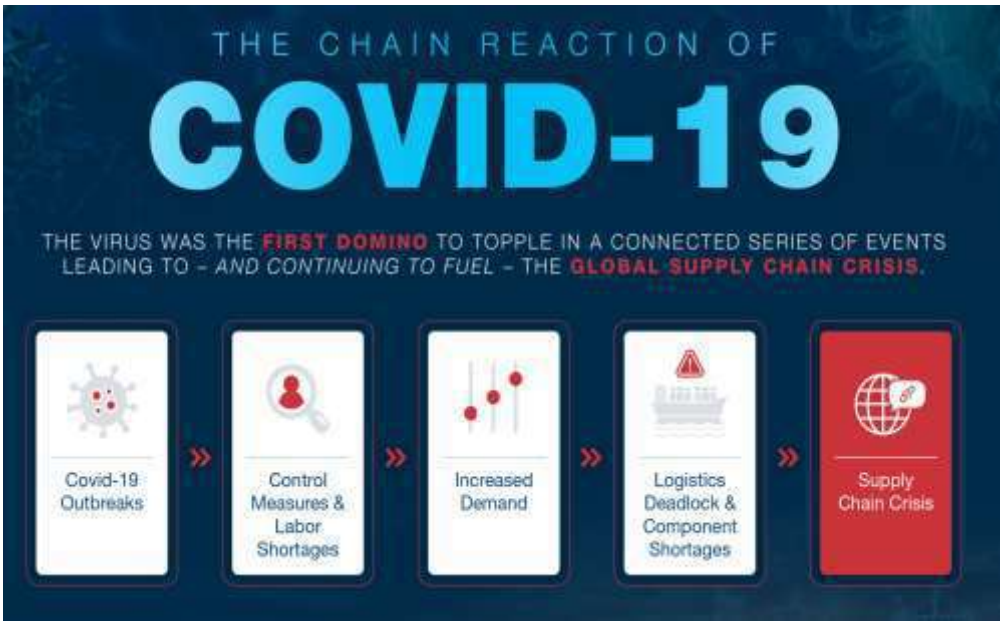
■ Global Supply Chains and Vulnerabilities

Supply chain vulnerabilities are weaknesses in these networks that can be exploited, causing disruptions.

1.Cyberattacks
2.Geopolitical factors
3.Supplier-related risks
4.Global events

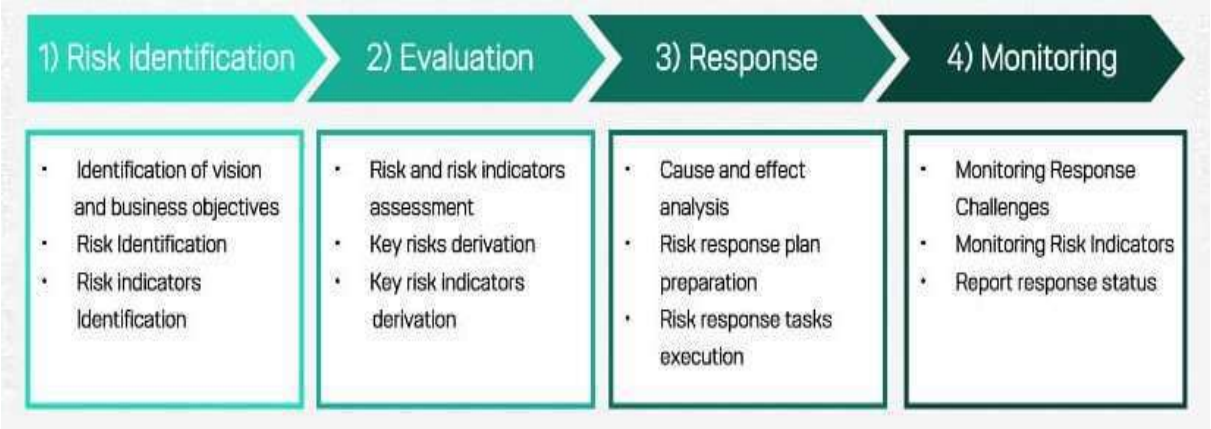
Some other challenges that can impact global supply chains include: -Increased material searcity, lack of supply chain visibility, increased freight prices, port congestion and environmental and social problems.

■ Impact of Global Supply Chain Disruptions, Especially Post-Covid-19



■ Risks Associated with Reliance on Specific Suppliers Or Production Sites

The potential for financial losses or disruption company operations that can occur when working with third-party organizations, particularly suppliers.



■ Solutions and Innovations In Supply Chain Management

1)Last-mile delivery
2)Self -service / do-it-yourself logistics
3)Collaborative mobile robots
4)Truck platooning
5)Blockchain
6)Tagging, sensors and geolocation technologies
7)Big data and AI

■ Adoption of Advanced Manufacturing Techniques

Advanced manufacturing techniques (AMT) are innovative technologies and techniques used to create new products or processes or modify existing ones. The use of AMT can help manufacturing gain a competitive edge in the global market.

1.Additive manufacturing

Methods like 3D printing powder-bed laser printing, and fused deposition. modeling can create complex assemblies from a single material.

2.Big data processing

Manufacturers can use large data sets from various business areas.

3.Factory automation

Factory automation can tighten process control, minimize human error, and automate quality assurance procedures.

4.Computer-controlled manufacturing processes

Valuable process data can be collected online for immediate analysis and rectification.

■ Role of Digital Tools In Improving Supply Chain Transparency And Security

Digital tools can improve supply chain transparency and security is including

1.Block chain

It can also enhance traceability, security, and efficiency.

2.Digital supply chain platforms

These platforms can improve communication and collaboration. between suppliers, manufacturers, distributors.

3.Automated data loggers

These can automate data collection, storage, and analysis.

4.Enhanced customer experience

The customer demands and ensures timely deliveries. This can improve customer satisfaction and loyalty.

5.Cost reduction

Digital transformation in supply chain management can lead to cost reduction.

◇ Data Security in Orphan Drug Research And Development

Important because the data is sensitive and can be used to identify individuals.

■ Importance of Data in Orphan Drug Development

1. Defining rare diseases
2. Identifying patients
3. Guiding clinical study design
4. Improving patient management
5. Understanding disease progression
6. Identifying gaps in care

● Types of data used in orphan drug development: -

1. Real-world data (RWD)

RWD can provide information on disease natural history, prevalence, and incidence.

2. Patient data

Patient data can be linked to external sources of data, such as mortality registries, biobanks, and imaging.

3. Registries

Registries can support research and regulatory endeavors.

■ Technological Solutions for Data Security

● Artificial intelligence and machine learning: -

These technologies can help to improve patient identification and diagnostic processes.

● Digital health platforms: -

These platforms can help to support patient management and adherence**.**

■ Challenges and Risks in Data Management

1. Data security
2. Data quality
3. Data privacy
4. Compliance
5. cybersecurity
6. Lack of data governance
7. Data loss
8.Data silos: - Data silos can be a challenge in data management.

■ Ethical Considerations and Regulatory Compliance

1.Transparency
2.Preventing harm
3.Fair treatment of employees
4.Respect for stakeholders
5.Building public relations

■ Technological Solutions for Data Security

1.Encryption
2.Firewalls
3.Access controls
4.Endpoint security
5.Antivirus software
6.Authentication
7.Network security
8.Hardware-based security

■ Application of Encryption, Data Anonymization, And Cybersecurity

Measures

1.Encryption

Transforms data into an unreadable format using a secret code that can only be unlocked with unique digital key encryption can help: -

a. Maintain data integrity
b. Adhere to regulations

2.Data anonymization

3.Cybersecurity measures

◇ Transparency in Orphan Drug Pricing and Reimbursement

Pricing: - The pricing of orphan drugs follows the same basic economic principles as general drug pricing.

•Manufacturers set the price to recover research and development (R&D) costs and achieve a desired profit margin and the price reflects the drug's value to patients, market factors such as the availability of alternative treatments, and the regulatory and reimbursement framework in a given country.

Reimbursement: - Evidence derived from economic evaluations is used to inform pharmaceutical reimbursement decisions in many countries.

•It has been recommended to allow greater use of surrogate outcome measures for orphan drugs if clinical data are incomplete, but impose at the same time a commitment to continue research.

■ Economics Models and Pricing Strategies

1)High and low-price strategies

High price is accepted if it agrees with the value of the product perceived by the customers, otherwise such a strategy leads to commercial failure.

2)Margin, price and selling level

Price influences profit margins and can also impact costs due to scale effects. While higher prices lead to greater profit per item, they may reduce sales volume, potentially driving up costs. Conversely, lowering prices can boost sales, which may reduce production costs due to economies of scale.

3)The selling curve

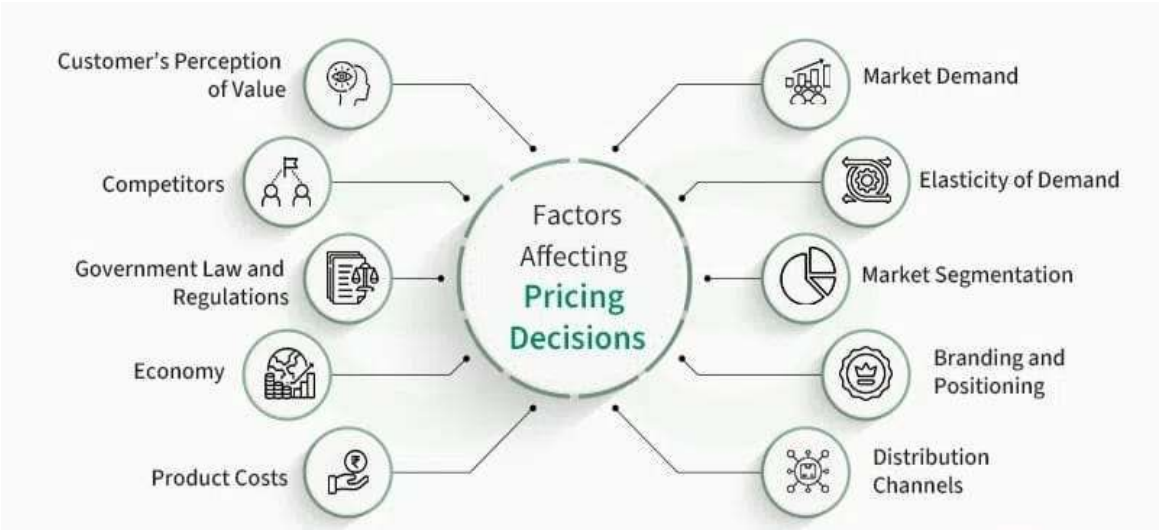
The selling curve, also known as the demand curve, illustrates the relationship between an item's price and the quantity customers are willing to buy within a

specific period. It is typically assumed that the business environment remains stable throughout this period.

4)Price strategy in oligopoly markets

An oligopoly market is a market dominated by a small number of providers. Each provider (firm) is aware of the actions of the other providers (competitors) and the actions of one provider influence the others.

■ Factors Affecting Pricing Decisions for Orphan Drugs



■ Controversies and Criticisms Surrounding High Orphan Drug Prices

1)Monopoly: -Marketing exclusivity gives a monopoly to the manufacturer as no other company is allowed to market the orphan drug during the exclusivity period.

•The monopolistic power is strengthened by the fact that no alternative health technology exists for many orphan drugs.

2)Price variation between countries: -

A study compared prices of ten orphan drugs between 25 EU countries. Price data originated from pharmaceutical industry, health authorities, retail or hospital pharmacies, and national databases.

•Some domestic pricing and reimbursement policies provide incentives to maximise prices of orphan drugs.

3)Costs of R&D and market access: -

The high price of orphan drugs also derives from the cost of the R&D process and of market access procedures. R&D of drugs is a very expensive process associated with a high attrition rate of potential products.

•A European analysis of orphan drug prices in 25 countries found that the price of an orphan drug is higher for a disease with a lower prevalence.

◇ Need of Transparency in Pricing

■The Role of Transparency in Building Trust with Patient, Healthcare Providers, And Payers

1)Building trust with patients: -

Building trust with patients involves being attentive, demonstrating competence, and showing genuine care.

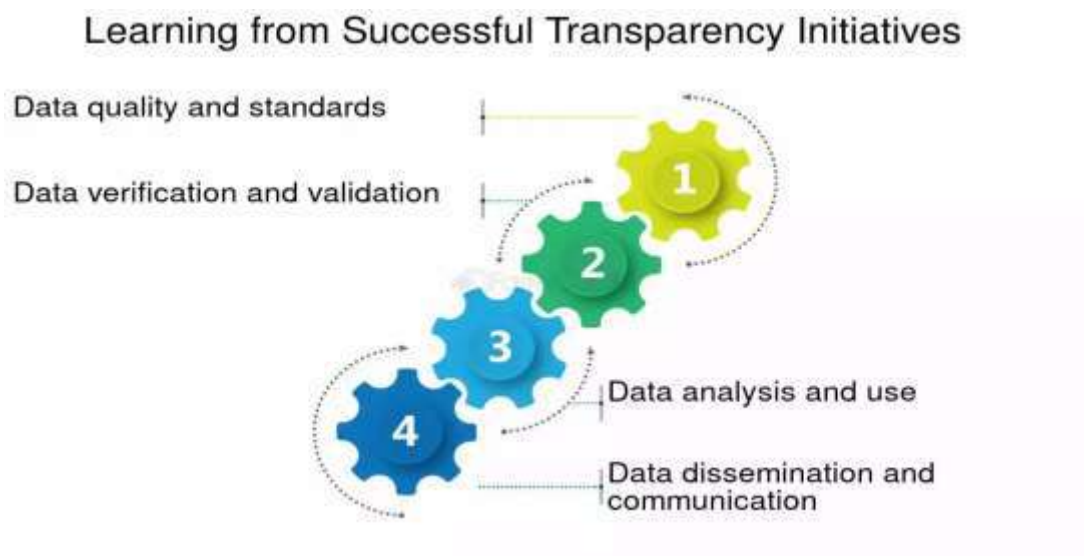
2)Healthcare providers: -

A healthcare provider is a licensed person or organization that offers healthcare services, including diagnosis and treatment.

3)Provider-payer relationships: -

Transparent policies and financial dealings can help improve the relationship between payers and providers.

■ Example of Transparency Initiatives



■ Innovations Pricing Models and Reimbursement Strategies

☆Innovations Pricing Models: - These models go beyond traditional cost- plus or competition-based pricing. They can be tailored to align with customer segments, market segments, or specific value propositions.

☆Reimbursement Strategies: - Reimbursement strategies allow patients to apply for claims after medical treatment is complete and bills are settled. This allows patients to focus on rest and recovery instead of administrative problems.

■Value-Based Pricing, Risks-Sharing Agreements, And Other Alternative Pricing Models

▪Value-based pricing (VBP) and risk-sharing agreements are two alternative approaches that can be used to set prices for orphan drugs.

1.Value-based pricing: - Value-based pricing is the cost of a treatment to the benefits it delivers to patients, healthcare systems, and society. This approach encourages innovators to create significant advancements over current treatments.

2.Risk sharing agreements: - Similar to insurance, where the insured pays a premium in exchange for the insurer's promise to cover the costs of certain losses.

◇ Future Direction and Recommendation

1)Policy Recommendations: - Policy recommendation is a structured suggestion aimed at resolving a particular issue, challenge, or objective within a specific setting, such as in government, business, or an organization is also known as policy recommendation.

■ Suggestion for Policymaker to Address Supply Chain, Data Security, And Pricing Transparency Challenges

☆ Supply Chain Challenges

1.Encourage Local Production: -Provide financial support like tax cuts and grants to promote domestic manufacturing and reduce reliance on imports.

2.Diversify Sources: - Work with multiple countries to avoid disruptions caused by depending on a single supplier.

3.Ensure Ethical Practices: -: Enforce stricter rules to prevent exploitation, unsafe working conditions, and environmental harm in supply chains.

4.Support Small Businesses: -Help smaller companies adopt advanced technologies and meet global standards through funding and training programs.

☆ Data Security Challenges

1.Adopt Strong Data Protection Laws: -

Align with global standards like GDPR to create clear rules for handling and protecting data.

2.Improve Cybersecurity Measures: -

Require companies to use encryption, multi-factor authentication, and conduct regular security audits.

3.Monitor Vendors' Security: -Make sure businesses evaluate and oversee the security of third-party vendors.

4.Prepare for Cyber Threats: - Establish national centers to help businesses defend against cyberattacks and offer training programs to boost cybersecurity awareness.

☆ Pricing Transparency Challenges

1.Make Pricing Clearer: - Require businesses to explain the full breakdown of their pricing, including hidden fees and charges.

2.Stop Unfair Practices: - Enforce laws to prevent price-fixing and exploitation, especially during emergencies.

3.Use Technology to Help Consumers: -

Develop tools that allow consumers to compare prices and understand costs easily.

2) Industry Innovations

● Emergency Technologies: -

1.Artificial Intelligence (AI) and Machine Learning.
2.Satellite Communication Systems.
3.Real-Time Data Analytics and Big Data.
4.Predictive Analytics for Disaster Management.
5.Supply Chain and Logistics Optimization Tools.
6.Industry-specific Innovations.
7.Telemedicine and Remote Diagnostics.

● Potential Impact

1.Faster response times: - Innovations such as drones and AI can help make quicker decisions and improve rescue efforts, which reduces the impact of emergencies.

2.Better preparedness: - Advanced forecasting and prediction technologies help both authorities and citizens prepare more effectively, reducing damage and saving lives.

3.Increased safety: - Wearables and robots keep first responders safer by limiting their exposure to dangerous situations and enhancing their ability to perform their tasks.

4.Cost efficiency: - Innovative technologies can reduce the costs of large-scale emergency responses by making resource use and response efforts more efficient.

3) Patient-Centered Approaches

Patient-centered approaches focus on providing care that is respectful of and responsive to the individual needs, preferences, and values of patients.

●Emphasis on patient advocacy, collaboration with rare disease organizations, and ensuring patient access to treatment.

Patient advocacy focuses on supporting patients' needs and ensuring their voices are heard in healthcare decisions. Working with rare disease organizations helps raise awareness, promote research, and provide resources for those with rare conditions. Ensuring patients have access to treatment means removing obstacles like cost or availability, so they can receive timely and effective care. Together, these efforts improve care quality and health outcomes, especially for those with rare diseases.

CONCLUSION

It is both challenging and crucial to ensure the commercial sustainability of orphan drug development, in order to prevent the system from collapsing. Incentives such as government grants, tax credits and extended market exclusivity have successfully encouraged innovation despite the high costs and limited patient populations. However, sustainable long-term practice means finding the equilibrium point of profits against affordable and accessible treatments. Equally important, some of the issues which need to be addressed are supply chain efficiency, data security and transparency. A resilient supply chain guarantees the prompt arrival of these

essential treatments, while enhanced data security safeguards sensitive patient and corporate data, engendering trust. Openness regarding pricing, clinical trials, and regulatory processes can enhance collaboration and public trust. We need to work on these challenges together to ensure that the orphan drug industry can continue to innovate and deliver life-enhancing and saving treatments, while ultimately promoting a fairer and more sustainable healthcare system.

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