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# To study regulatory approval of medical device used for respiratory disease in India and USA

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**Abstract**
Infections of the respiratory system are well-recognized as major contributors to death and disability on a global scale. Farmers in several countries throughout the world often engage in ACRB (Acronym for agricultural crop residue burning), the practice of burning agricultural crop remnants. Airborne particles with the potential to be harmful to human health are released when ACRB is activated. Inhalation can cause the discharge of these particles into the environment. Asthma, allergic rhinitis, chronic obstructive pulmonary disease, and rhinosinusitis are just a few of the many chronic respiratory ailments that are on the rise in the Asia-Pacific region. Some examples of diseases that fit within this group are rhinosinusitis, COPD, and allergic rhinitis, however this is by no means an entire list. The Asia-Pacific Burden of Respiratory Diseases project investigated the prevalence of asthma, COPD, allergic rhinitis, and rhinosinusitis across the Asia-Pacific region, with a focus on India, as well as the financial costs associated with these conditions. India was highlighted as the primary target of much of the interest generated by this investigation.

**Keywords:** Respiratory, chronic, asthma

## Introduction
The healthcare system in India has undergone several substantial changes in the 21st century as a direct result of the shifts. By 2025, the value of this area of India's economy is projected to reach $280 billion, thanks to a compound annual growth rate of 10% over the following decade. The following decade will see expansion at this rate. When compared to the United States ($9,403), the European Union (EU) ($3613), China ($4200), and the global average ($1061), India's healthcare expenditures in 2016 were a pitiful $75 per person. The healthcare market in India, now valued at $128 billion, is expected to grow by 12% over the course of the next four years.

When it comes to healthcare, medical devices have become an integral part of the market in every growing nation that sets a premium on the quality of its healthcare system. This is true of both first-world nations and those on the cusp of development. This is true even if the nation does not prioritize improving the quality of its healthcare system. There are a wide variety of potential uses for these in the field of medicine, including screening, diagnosis, treatment, rehabilitation, and monitoring. Numerous further uses exist as well. The list of possible further applications is enormous. The medical equipment market in India has recently jumped from 21$^{st}$ to 20$^{th}$ in the globe. If the industry continues to expand at its current 15% CAGR, it is projected to be worth $50 billion by 2025. This is the estimate for the size of the market right now [1, 4]. Different types of electronic equipment have vastly different available market shares in India. The diagnostic imaging devices industry dominated the market, taking for 31% of the total. Next follows the industry of medical equipment and appliances (34%), then the industry of consumables and implants (19%), and finally the industry of patient assistance and other businesses (16%). Around 70% of India's medical equipment is imported, according to some estimates. As can be seen in there is a huge window of opportunity for domestic makers of medical equipment to reduce the gap between their output and that of imports by raising both output and income within their home country. There is a lot of time and effort required in the current process of developing new medical devices. One of the world's most efficient processes for the approval of medical devices is now possible thanks to the Indian Medical Device Rules (IMDR) 2017 and the

Medical Devices (Amendment) Rules, 2020. All aspects of medical device regulation, from classification to registration to production and import and labelling and sales and post-market compliance, are covered here.

Additional obligations for guaranteeing the safety of medical devices have been placed on the European Commission, competent authorities, and notified organizations since the implementation of the Medical Device Regulations (MDR) and the *in vitro* Diagnostic Regulation (IVDR) in 2017. All licensed medical devices must now undergo recertification testing to ensure they continue to meet standards. For the sake of maintaining quality, this is crucial. When determining the usefulness and dependability of a medical equipment, the first and most important stage is a clinical evaluation. This assessment is being conducted in the European Union, widely recognized as the most demanding regulatory organization on the planet. It is also a vital tool for determining the remaining useful life of the machines and always keeping a close eye on them. This may be achieved by monitoring them constantly. Although the IVDR's implementation date of May 26th, 2022, will not be pushed back, the European Parliament and the Council of the EU have just recently (April 23, 2020) agreed to a proposal to extend the transitional period of the MDR by one year (to May 26th, 2021). As a result, the IVDR will become law on May 26, 2022. The new criteria are modelled after the rigorous requirements set by the FDA in the United States and will serve as the guiding concept for the approval process. While post-market norms do exist, there are still certain limitations on their use in India. The IMDR states that only during the approval process may clinical assessment criteria be utilized in the production of specific medical devices in India.

**A new era for medical device regulation**

Because of the critical nature of patient health and safety, medical device production occurs in a strictly controlled environment. These components are also essential for meeting the most demanding norms and regulations in the business world. While India has had drug rules in place for quite some time, the country lacks a clear and comprehensive framework for regulating medical devices. Despite this, the Indian medical device regulatory system has been extremely busy during the past few years. The government has been a driving force behind this initiative. The IMDR standards for medical devices are developed by the Medical Devices and Diagnostics Division of the Central Drug Standard Control Organization (CDSCO). The International Medical Device Regulations (IMDR) contain these criteria. These guidelines were initially introduced to the public in January of 2017, and they went into effect one year later in January of 2018. Originally scheduled to go into effect in April of 2020, the International Medical Device Regulations (IMDR) addendum Rules, 2020 were made available to the public in February of that year. They were an afterthought, added to the IMDR as a coda. A new subsection labelled "Registration of certain medical devices" was introduced to the statute after the 2020 amendment was made public. The introduction of the Indian Medical Devices Regulations (IMDR) and other supporting recommendations has allowed India to take its first step towards greater patient safety with respect to medical devices, even though many medical devices are currently regulated as pharmaceuticals under the Pharmaceuticals and Cosmetics Act of 1940. India can make this progress because of the IMDR and the other suggestions. Because of this, India can start this first step towards better patient safety. India has been able to because of this. Because India is such a large consumer market, this is quite consequential. It is likely that any future amendments to the IMDR would focus on filling up the gaps that, if addressed, would have rendered these rules equal to the EU's MDR and IVDR, as these are the most contemporary international standards for the safety and performance of medical devices. The MDR and IVDR of the EU are the most up-to-date international standards for the quality and effectiveness of medical equipment, thus this makes sense.

**Professional evaluation or clinical performance investigation**

Clinical trials are necessary for determining the safety, efficacy, and risks associated with a novel medical technology in the context of actual patients. The process outlined here is quite like that used when approving new medications. Collection of samples from human volunteers is the first step in a clinical performance evaluation of a newly designed IVDMD. Before the IVDMD may be utilized, it must undergo this examination. Before this is done, the IVDMD's potential value cannot be determined. The clinical investigation strategy and the clinical performance evaluation plan are used to provide guidance for the actual clinical research and assessment, respectively. As can be seen in [Figure 5], there is a substantial quantity of paperwork needed for both the clinical investigation and the clinical performance evaluation plan. Throughout the duration of the treatment, the subjects' legal rights must be safeguarded in a way compatible with the ethical standards described in the Declaration of Helsinki, in addition to their physical and mental health and safety. This responsibility is inherent whether or whether the subjects volunteer for the study.

Samed (2014) [23] argues that the healthcare industry is growing increasingly dependent on the use of various medical devices for the treatment and diagnosis of a broad variety of medical disorders. This is because to the improving reliability and accuracy of medical tools.

There have been indicators of a growing market for medical devices used for health monitoring, and with that, a rise in the likelihood of experiencing problems because of using this equipment. Many new manufacturers have entered the Indian market with the intention of making a profit by producing items that do not meet the standard that has been set by the industry because of the government's failure to pay enough attention to the regulation of medical devices. As a result, there are more low-quality medical products on the market. Nebulizers, sphygmomanometers, pulse oximeters, and glucose meters are just a few examples of the many user-friendly medical equipment currently on the market. As a result, individuals can assume control of their health in a method that doesn't need a lot of time or money. Dialysis machines, ventilators, infusion pumps, and other cutting-edge medical equipment are increasingly being used outside of traditional healthcare facilities. Although these devices are used in settings outside of hospitals, strict regulations govern their application. Since patients now require the aid of healthcare staff to utilize these gadgets, scientists are currently working hard to enhance their

design. Patients will have more say in their care because of this.

Due to the high cost of patient treatment and the emphasis put on quality and safety, the healthcare industry is argued to be a substantial service sector by McFadden and colleagues who performed study on the issue. Any item that may be used alone or in conjunction with other items to achieve the manufacturer's stated medical goals is considered a medical device. This includes tools, appliances, machines, equipment, apparatus, implants, and *in vitro* reagents. Pacemakers, defibrillators, infusion pumps (both intravenous and intramuscular) and infusion sets are all examples of medical equipment. Any instrument, appliance, machine, equipment, apparatus, implant, or similar *in vitro* reagent is considered a medical device by the World Health Organization (WHO). The WHO came up with this definition.

Injury care (Including prevention, diagnosis, monitoring, and compensation), medical care (Including tracking, diagnosis, and care), and accident care (including compensation)

- *In vitro* examination of human body specimens provides the necessary information for: modifying, replacing, studying, or supporting the anatomy or the physiological process; supporting or maintaining life.
- Monitoring the design of medical equipment.
- Disinfecting medical equipment.
- Dissipating medical equipment.

Pharmacology, the immune system, and metabolism cannot perform the primary activity intended to take place on a human body; nonetheless, these fields may be helpful in achieving the intended effect. (World Health Organization; Medical Supplies)

There are many different methods to classify medical equipment, which can range from a basic needle to a complicated life-support unit. In addition to screening, diagnosing, and treating patients, medical equipment is also used to assist patients return to their usual lifestyles and monitor their health indicators more regularly, with the goal of maintaining good health and avoiding future illnesses. Because of technological advancements, medical devices are increasingly capable of performing a wide variety of tasks, elevating the standard of care across the board.

**Airways and Breathing System Illnesses**

Respiratory infections impact individuals of all ages, and they are one of the most common kinds of both acute and chronic sickness worldwide. Among the most frequent illnesses, respiratory problems are consistently towards the top. People are more likely to acquire respiratory diseases if they are exposed to dangerous substances, have an unhealthy lifestyle, become unwell frequently, or have specific genetic features. Some of the most common disorders affecting the respiratory system are ARDS (acute respiratory distress syndrome), COPD, asthma, sepsis, and the recently found COVID-19, which is caused by infection with the Sars-CoV-2 virus.

**Review literature**

Major contributors to the global sickness burden include respiratory disorders. We are doing a field study in India to learn more about the seasonal patterns and relative burden of various respiratory illnesses. Methodological considerations for a point prevalence survey of respiratory disease in India are described here.

The worldwide toll of chronic illnesses appears to be steadily increasing. It is estimated that over 500 million individuals worldwide are afflicted by them. The Parts and the Methods The study set out to quantify the prevalence of COPD in India's rural communities. The British Medical Research Council's questionnaire was adapted, and then used in a study of the general population. Then, they were given Wright's miniature peak flow meter to use in determining the peak expiratory flow rate and establishing a diagnosis of chronic obstructive pulmonary disease.

In 2016, Susan Horton It is becoming more worrying that adult respiratory disorders, especially those linked to chronic respirator y disease, are a major cause of morbidity and mortality in developing nations, as reported by Murray and Lopez (1996) [24]. For a very long time, tuberculosis has been the leading cause of death in adults owing to respiratory illnesses. Despite improvements in treatment and prevention methods, it still causes the deaths of far more people than it should. In contrast, the major focus of this chapter will be on the rising worldwide burden of different acute and chronic adult respiratory illnesses.

**Objective of the study**

1. Consider looking into how medical gadgets go through the approval procedure.
2. to investigate the various routes of drug administration used to treat respiratory disorders.

**Acute respiratory distress syndrome (SARS).**

In the worst cases, the acute respiratory distress syndrome (ARDS) can be deadly. Infectious pneumonia is the leading cause of ARDS and death worldwide. There is a vast range of potential causes for ARDS, although pneumonia is by far the most common. Pathogens including Escherichia coli, Streptococcus pneumoniae, Klebsiella pneumoniae, and Staphylococcus aureus all contribute to the development of pneumonia. This leads to inflammation, leukocyte infiltration into the airways, and decreased blood oxygen levels.

ARDS has a complex etiology and course, making it difficult to discover effective treatments. Mechanical ventilation, fluid management, neuromuscular inhibition, and antibiotics are currently the most widely employed treatment modalities.

**Chronic obstructive pulmonary disease is what we mean when we say COPD.**

Chronic obstructive pulmonary disease (COPD) is already a major public health issue, and it is predicted to grow in prevalence as the world's population ages and as more individuals begin using tobacco products. Chronic obstructive pulmonary disease (COPD) was the fourth leading cause of mortality in the United States in 2016, with 3.17 million deaths out of a total of 251 million cases globally. This was the underlying cause of CVD, cancer, and stroke. The biggest risk factor associated with COPD is exposure to airborne pollutants and gases. When this happens, it triggers an inflammatory response in the lungs and airways, which ultimately results in parenchymal tissue loss and the onset of emphysema. Unfortunately, there are currently no treatments available that have been shown to slow or stop the deterioration that comes with the disease.

Some of the symptoms of chronic obstructive pulmonary disease (COPD) may be alleviated by regular use of inhaled bronchodilators.

**The Asthma**

Asthma is a lifelong, non-contagious disorder caused by chronic inflammation of the airways. Asthma affects people of all ages, and its symptoms can worsen or improve throughout the course of a person's life. According to research presented in the 2018 Global Asthma Report, the disease now affects an estimated 339 million people throughout the world. The sickness has several different phenotypes, each of which has its own distinct etiology and pathophysiology. Risk for the disease is thought to arise from both genetics and the surrounding environment.

Allergen stimulation factors including dust mites and pollen, as well as perennial allergens like viral infections, cold air, and exercise, can trigger the immune response known as T help cell type-2 (Th2), which is linked to asthma. These factors may initiate a chain reaction leading to chronic airway inflammation. Edoema, increased mucus production, and bronchospasm are all symptoms of an overabundance of Th2 cells in the bronchial tree. Currently, asthma therapy only includes pharmacological intervention in the form of inhaled corticosteroids (ICS).

**Septicemia**

Patients in non-coronary intensive care units in the United States often succumb to their illnesses because of sepsis. High rates of illness and death are commonly connected with this major issue. The additional difficulty that sepsis presents is substantial. Uncontrolled inflammation is a hallmark of sepsis and one of its most recognizable signs. Sepsis is an irregular condition that can have far-reaching effects on the body.

Sepsis is caused by an infection that has travelled to other parts of the body and set off a cascade of responses in the body that ultimately lead to organ failure. The most common source of these diseases is a respiratory tract infection, the most common of which is pneumonia. Complications like ARDS get worse in tandem with respiratory failure. Patients with sepsis are more prone to nosocomial infections because they lose their sensitivities, become unable to clear infection, and worsen as their condition worsens.

Early identification, antibiotics, lung protection ventilation, and strategies to minimize nosocomial infections are all current therapy for the condition; but, due to the complex nature of sepsis, there is no standardized strategy. All these methods are designed to make things better. Seeing as there are no approved therapeutic drugs for the treatment of sepsis, there is an obvious need for the development of novel therapeutic approaches. This is true despite progress in understanding the biology of sepsis.

**COVID-19**

An Extreme Case of Acute Respiratory Distress It has been determined that Coronavirus 2 (Sars-CoV-2) is the etiological agent of the 2019 Coronavirus disease pandemic, also known as COVID-19. On March 11, 2020, the World Health Organization (WHO) declared that the virus presented a threat to public health and had reached an emergency level, two months after the first documented case occurred in Wuhan, China. The lungs are COVID-19's principal target. Overstimulation of this defensive system in response to harmful substances can cause an unchecked inflammatory response that severely damages lung tissue. However, under normal circumstances, inflammatory cytokines like macrophages infiltrate the lungs to provide protection. A complex and coordinated process facilitates the "cytokine storm" hyper-reaction that occurs during COVID-19 progression. There are three stages to this process: (i) the appearance of lymphocytes to the virus is altered by antigen-presenting cells like macrophages becoming activated; (ii) pro-inflammatory factors become activated because of viral RNA replication within the host cell; and (iii) lymphocytes undergo apoptosis and immune evasion because of lymphocyte viral invasion.

There was no vaccine or therapy for COVID-19 at the time this report was written; the only known measures were prevention of infection and supportive care. To maximize the therapeutic effect of multiple therapeutic strategies, which may influence antigen-presenting cell activation, viral RNA replication with cells, and lymphocyte apoptosis, among others, a pleiotropic agent is likely necessary due to the complexity of the disease. Antivirals, antibiotics, and agents like hydroxychloroquine are all being studied for their potential applications. However, these choices only affect one target at a time. The effects of COVID-19 on global health and the economy have been significant, and they will remain so until a novel and effective therapy is developed. There is a lot of hope for the utilization of cellular treatments like MSCs and exosomes as an alternative means of treating COVID-19. This is because COVID-19 can evade the body's natural antiviral defenses and because these therapies guard against and repair pulmonary harm.

**Alternative Drug Delivery Systems for the Treatment of Lung Diseases**

One of the many factors that determines the success of lung treatment is the delivery method used to provide the medicine. Several drug delivery systems have been developed with the dual aims of decreasing potentially harmful side effects and increasing the efficacy of the therapeutic benefits of medications used to treat respiratory diseases, the majority of which are administered via inhalation therapy.

Direct targeting of drugs to the airways by inhalation as the primary route of delivery allows for rapid absorption of low-dose medication and may limit the occurrence of systemic bioavailability. In contrast, intravenous (IV) administration entails injecting drugs directly into blood vessels; this bypasses the effects of gastrointestinal absorption and the liver's first pass before the drug reaches the lungs, hence increasing the available dose. Furthermore, it is hypothesized that EVs and MSCs aggregate or clump together in the damaged lung microvasculature, which poses a risk of mutagenicity and oncogenicity.

This non-invasive delivery method may be less expensive than intravenous (IV) administration because it requires a smaller dose of expensive medications to achieve the same local delivery drug concentration to the lungs as IV administration does.

When compared to intravenous or oral delivery, inhalation therapy is preferable because to its high pulmonary efficacy, rapid onset of action, and reduced risk of adverse effects.

To achieve the direct targeting of the lungs and the rapid onset of the medication, aerosol-generating devices are used. These include, but are not limited to, pressurized metered dose inhalers (pMDI), dry powder inhalers (DPI), soft mist inhalers (SMI), and nebulizers, which can be air-driven jet nebulizers (JN) or the newer closed-circuit vibrating mesh nebulizers (VMN

**Choosing the Right Delivery Method for New Combination Products**

Although developing ATMP/device combinations is a challenging endeavor, it may be minimized by beginning the process as early in the project as feasible with the screening and selection of the aerosol-producing devices. The following data will have a major impact on the chosen device, thus it's important to assess it holistically. There are several technological tools that should not be used in conjunction with a patient, an intervention on a patient, or a therapeutic procedure.

The patient might be an adult, a child, or even a brand-new baby. The respiratory characteristics (breaths per minute, tidal volumes, inhalation to exhalation ratio, peak inspiratory flow rate) can affect the aerosol dosage delivered to the lungs, which in turn is affected by the patient type and the severity of the sickness. It is generally accepted that the infant lung is the organ with the most difficulty in delivering therapeutically significant doses of drugs; hence, treatment choices may be limited.

Oxygen supplementation using a mouthpiece or face mask in patients who are spontaneously breathing; or ventilatory support with invasive or non-invasive procedures (full masks, nasal pillows, nasal cannula) are all examples of patient treatments in which the ATMP will be administered. There will be a direct relationship between each intervention and the lung dose, and the device may not be able to handle all of them at once. When high-flow nasal therapy or mechanical ventilation is being given, for instance, DPI should not be used. The length of time the patient has been receiving ATMP medication is another factor to think about. In this case, keeping your technological prowess at the same level as before is crucial. If therapy is started ahead of time and kept up no matter how far along the disease has progressed, patients may need a wide variety of interventions. Nebulizers appear to be the only piece of equipment that can be utilized simultaneously across all these therapies, according to an assessment of the relevant literature. However, as will be discussed further below, VMN consistently delivers the largest amount of formulation to the lung across the interventions, and this provides an example of how the appropriate selection of delivery device/technology can streamline combination product development and potentially facilitate expanded ATMP prescription throngs.

Targeted site of action inside the respiratory tract: the size of the aerosol droplets will be key in identifying where within the respiratory tract the therapeutic drug will have the most favorable impact. Smaller droplets can travel farther and reach more peripheral regions of the lung than larger ones can. Adequate targeting, accomplished by the selection of aerosol droplet sizes, has been shown to significantly increase the efficacy of inhaled drug therapy for basic bronchodilators. Aerosol deposition and dispersion are known to be affected by several patient-specific variables, such as the patient's breathing rhythm, posture, and health.

Designing a Formula: Inhaled medications are often formulated as liquid solutions, liquid suspensions, or dry powders. When it comes to ATMPs, the quantity of cells or exosomes will likely determine their effectiveness, rather than the milligrams per kilogram of medicinal mass. For example, stem cells are highly unlikely to be administered as a dry powder (through DPI) or at the extremely low, microliter range dose levels typical of pMDI and SMI. However, spray drying has been shown to be feasible for exosomes, so it's plausible that it may be appropriate for MSC-derived proteins and peptides if enough were provided. Despite this, nebulizers are virtually always the best choice for use in a critical care situation. The technology of nebulizers isn't without its limitations; for instance, JN nebulizers are optimized for aerosolizing the suspension buffer. Due to the high cost of wasted stem cells and exosomes, they may not be suitable for a JN's commercial combination in a specific formulation. The usage of JN, however, has been claimed to work with MSCs. Table 1 provides an overview of the formulation properties of ATMPs and their potential compatibility with the various aerosol generators employed alone. But as was mentioned before, compatibility isn't everything when it comes to determining whether a gadget is fit for purpose. When deciding which gadget to utilize, for example, the patient's level of involvement should factor into the mix.

**Conclusion**

The comprehensive planning of healthcare-related topics requires the examination of a new type of data. Despite several challenges, with the help of different technologies, considerable data collecting is achievable in developing nations like India. The information gained from this research has the potential to significantly advance the science of respiratory epidemiology and serve as a road map for future global multicenter investigations.

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