AMERICAN JOURNAL OF PHARMTECH RESEARCH
Journal home page: http://www.ajptr.com/

Regulatory Requirements For MRNA-Based Therapeutics As Per CDSCO (India) in comparison with Swissmedic (Switzerland)

Ashok Kumar P*, Bhargavi S, Bhavana L, Lochan Gowda BT, Meghana CM, Pooja Priya D

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 feet Road, Batwadi, Tumkur-572103, Karnataka, India.

ABSTRACT

mRNA based therapeutics have evolved emerged as a promising platform in modern medicine because they facilitate provisional production of specific protein within cells. Their applications extend beyond infectious disease vaccines to cancer immunotherapy, protein replacement, gene editing, regenerative medicine, and treating of genetic disorders. Although, the successful development of these products depends on appropriate control of RNA quality, stability, delivery system, manufacturing processes, safety, and efficacy. This research focus on reviewing the regulatory requirements for m RNA based therapeutics in India and Switzerland with particularly focus on the central drug standard control organization (CDSCO) and SWISSMEDIC. The study compares their regulatory framework, approval pathways, manufacturing requirements, quality and storage condition, development criteria. India follow its existing drug and biological product regulatory framework, while Switzerland provide a structured approach for innovative and advanced therapeutics products. The comparative assessment indicates that India has considerable potential for cost effective manufacturing and expanding mRNA research, whereas Switzerland has a highly developed pharmaceutical and research environment. Continued improvement in regulatory guidance, manufacturing capability, product characterization, delivery technologies and safety monitoring may facilitate the wider development and adoption of mRNA-based therapeutics.

Keywords: mRNA therapeutics, cancer immunotherapy, CDSCO, SWISSMEDIC, regulatory framework.

*Corresponding Author Name: Dr Ashok Kumar P
Received 01 September 2026, Accepted 15 September 2026

Please cite this article as: Kumar AP *et al*., Regulatory Requirements For MRNA-Based Therapeutics As Per CDSCO (India) in comparison with Swissmedic (Switzerland). American Journal of PharmTech Research 2026.

INTRODUCTION

Messenger RNA is a single-stranded ribonucleic acid molecule that carries coding information required for protein synthesis. In a therapeutic setting, a designed mRNA transcript can be introduced into cells so that endogenous ribosomes produce a selected protein or protein fragment. This concept provides an attractive alternative to conventional protein administration because the biological product is generated within the target cell for a limited period. The uploaded source material identifies mRNA as a flexible platform for infectious diseases, cancer, genetic disorders and regenerative applications. The pharmaceutical interest in mRNA increased markedly after the clinical success of mRNA vaccines. More recent work has broadened the field toward protein replacement, personalized cancer vaccination and delivery of gene-editing components. Current literature emphasizes that the principal translational barriers are not limited to RNA sequence design; they also include extracellular stability, intracellular trafficking, tissue targeting, duration of expression and scalable manufacturing[1].

Figure 1: Therapeutic Applications of mRNA in Rare Genetic Disorders

Types of mRNA:

Prophylactic mRNA therapeutics mRNA vaccines; These vaccines are designed to prevent infectious diseases by inducing an immune response against specific pathogens; Pfizer-Bio NTech COVID-19 Vaccine (Comirnaty), Moderna COVID-19 Vaccine. Therapeutic mRNA vaccine. Therapeutic mRNA vaccines are used to treat existing diseases, particularly cancer, by stimulating the immune system to recognize and attack diseased cells; mRNA-4157/V940 Personalized Cancer Vaccine. Protein Replacement Therapy; In this approach, mRNA is delivered to cells to produce functional proteins that are absent, deficient, or defective due to genetic disorders.; MRT5005 for Cystic Fibrosis. Gene Editing Therapies; mRNA can be used to deliver gene-editing tools, such as CRISPR-associated proteins, into target cells. These tools enable precise modification or correction of disease-causing genetic mutations; NTLA-2001 for Transthyretin Amyloidosis. Cell Engineering Therapies; Cell engineering involves the use of mRNA to modify cells either inside

the body (in vivo) or outside the body (ex vivo) before transplantation; mRNA-engineered CAR-T Cell Therapy for Leukemia and Lymphoma. Regenerative Medicine; mRNA therapeutics can promote tissue repair and regeneration by encoding growth factors, signaling molecules, or regenerative proteins; AZD8601 (VEGF-A mRNA Therapy). Immunomodulatory mRNA Therapeutics; These therapeutics are designed to regulate or modify immune responses by encoding cytokines, antibodies, or other immune-related proteins; IL-12 mRNA Immunotherapy.

Molecular design and manufacture:

The activity of an mRNA medicine is strongly influenced by its molecular architecture. A therapeutic transcript generally contains a 5′ cap, 5`untranslated region, coding sequence,3`untranslated region and a poly(A) tail. These elements collectively influence translation, stability and degradation.

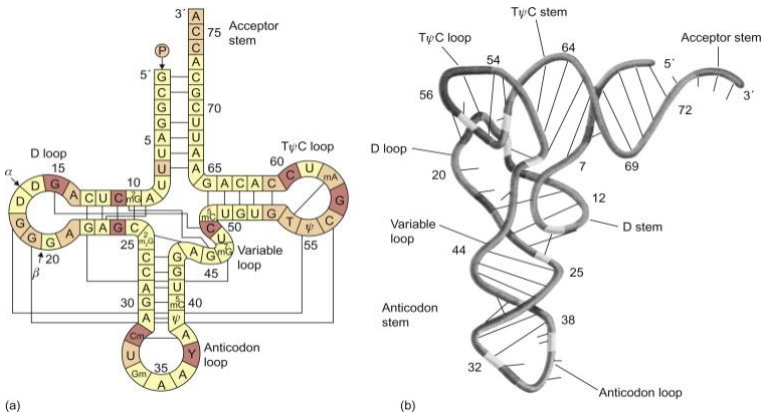

Figure 2: Functional Components of mRNA

5`Cap is a modified guanine nucleotide attached to the 5` ends of mRNA, it protects mRNA from degradation and helps initiate translation by ribosomes. 5` Untranslated Region (5`UTR) is located between the 5`Cap and the start codon, It regulates mRNA stability and translated efficiency .Coding sequence(CDS) contains the genetic information in the form of codons, directs the synthesis of a specific protein during translation.3` Untranslated region (3`(UTR) is located after the stop codon and before the poly(A)tail, it influences mRNA stability, localization, and translation regulation. poly(A) is a stretch of adenine nucleotides at the 3` ends of mRNA, it enhances mRNA stability, protects against degradation and promotes efficient translation.

Nucleoside modification and removal of unwanted RNA species can also reduce excessive innate immune activation and improve functional protein expression. Manufacturing commonly involves in-vitro transcription followed by purification and formulation. Quality attributes such as RNA integrity, sequence identity, capping efficiency, poly(A) characteristics and removal of double-stranded RNA impurities are important because they can influence potency and tolerability. Recent

reviews identify nucleoside engineering, improved purification and advanced delivery systems as major areas of pharmaceutical development[2].

Delivery and mechanism of action:

Naked mRNA is susceptible to degradation and has limited ability to cross biological membranes. Consequently, delivery technology is a major determinant of therapeutic performance. Lipid nanoparticles (LNPs) are among the best-established systems for protecting mRNA, promoting cellular uptake and facilitating cytoplasmic release. After administration, the carrier reaches target cells and is taken up mainly through endocytic pathways. The RNA must then escape the endosomal compartment and reach the cytoplasm, where ribosomes translate the encoded sequence into the intended protein. The mRNA is subsequently degraded through normal cellular pathways.

The transient nature of this mechanism is one of the principal advantages of the platform: protein production can be achieved without permanently changing the cellular genome. However, delivery remains a major bottleneck because efficient endosomal escape and tissue-selective distribution are difficult to achieve simultaneously. Recent research is therefore exploring organ-selective nanoparticles, alternative carrier systems and improved formulations to extend mRNA therapy beyond tissues that are readily reached by conventional LNPs.

Therapeutic application:

The range of potential applications is broader than prophylactic vaccination. In infectious disease, mRNA can encode antigens and stimulate both humoral and cellular immune responses. In cancer, personalized mRNA vaccines can encode tumor-associated or patient-specific antigens, while other constructs can modulate immune responses. The source material also describes protein replacement as an approach for disorders in which a functional protein is absent or deficient.

mRNA can additionally serve as a transient source of gene-editing machinery, including CRISPR-associated proteins. This strategy may provide a controlled method for producing editing components without maintaining their expression indefinitely. Other areas include regenerative medicine, cardiovascular repair, therapeutic angiogenesis, immune modulation and rare monogenic disorders. Current reviews confirm that these applications are being investigated alongside improvements in tissue targeting and personalized treatment[3].

Advantages and application:

Major advantages of mRNA therapeutics include rapid sequence-based design, transient expression, absence of a requirement for nuclear entry, and adaptability to different therapeutic proteins. The platform can therefore support personalized medicines in situations where conventional biologic manufacturing would be slow or difficult. The source material also

highlights rapid manufacturing, flexibility and non-integrating expression as important benefits. Important limitations remain. RNA is vulnerable to degradation, and delivery to specific organs or cell populations can be inefficient. Expression may be short-lived or variable, while repeated administration can create additional formulation and tolerability considerations. Manufacturing must also maintain consistent product quality at scale. Current research particularly focuses on improving stability, endosomal escape, tissue specificity and process stability.

Future perspectives:

The next stage of mRNA development is likely to depend on coordinated progress in RNA sequence engineering, chemical modification, purification, formulation and tissue-selective delivery. Emerging approaches such as self-amplifying RNA and circular RNA may provide alternative ways to increase or prolong intracellular protein production, while advanced nanoparticles may enable delivery to tissues beyond the liver. For pharmaceutical development, the central goal is no longer simply to make mRNA enter cells; it is to control where, when and for how long the encoded protein is produced. Better characterization of product quality, pharmacokinetics, biodistribution and immune responses will be essential for translating promising laboratory systems into reliable medicines. mRNA therefore represents a platform technology with the potential to complement vaccines, recombinant proteins, gene therapy and other precision-medicine approaches.

mRNA therapeutics provide a flexible method for temporary production of selected proteins inside cells and have already demonstrated substantial clinical value in vaccination. Their broader pharmaceutical potential includes cancer immunotherapy, protein replacement, gene editing, regenerative medicine and rare genetic diseases. Nevertheless, stability, delivery, tissue targeting, immune activation and scalable manufacturing continue to limit wider clinical use. Continued optimization of RNA chemistry and delivery systems should help overcome these barriers and may establish mRNA as a broader therapeutic platform for precision and personalized medicine.

Overview Of CDSCO:

The Central Drugs Standard Control Organization (CDSCO) is a national regulatory body for biological products, cosmetics and pharmaceuticals in India. The Indian government has announced its plan to review medical device and biological products under the Central Drugs Standard Control Organization (CDSCO). The CDSCO works under directorate general of health services. It’s headquarter is located at New Delhi FDA Bhawan kotla Road 110002. The is responsible for efficacy and safety and quality of biological products in the Indian markets the main aim is to protect and promote health

Objective Of CDSCO:

The various objectives of CDSCO are to uphold the public health by giving assurance about the safety, quality of the drugs in India. The CDSCO monitors the new drug by verifying the quality, manufacturing procedure and clinical trials and also monitors the post marketing changes. The CDSCO have the authority over import of drugs and CDSCO monitor the adverse reaction for the safety purpose.

The responsibility of CDSCO is

- New drug approval
- Regulation of biological products
- Approval to test certain pharmaceutical product
- Drug safety and adverse drug reaction
- Monitor drug standards
- Permission for trials

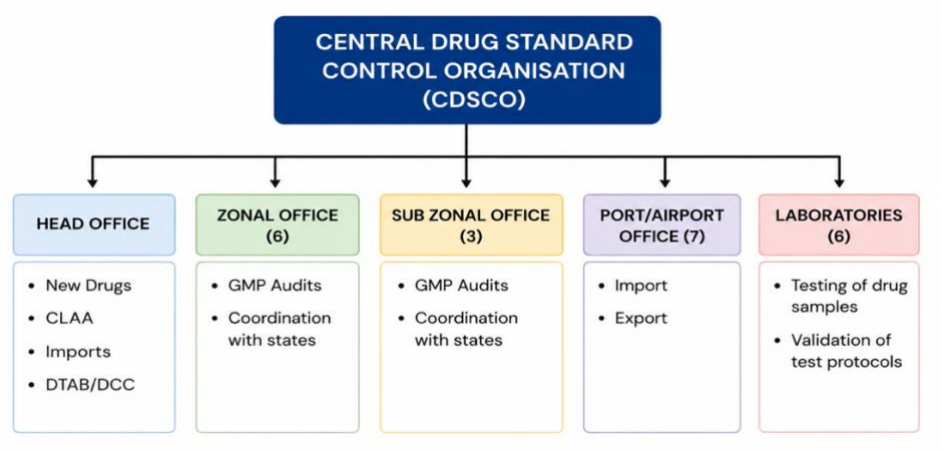

Figure 3: Organization of CDSCO

The CDSCO operate under government of India, Ministry of health science and Directorate general of health science. It is governed by drugs controller general of India. The CDSCO works under its headquarter which is present in New Delhi, along with 6 zonal office, 4 sub-zonal office, 13 port office and 7 central drug testing laboratories situated at different places in India.

OVERVIEW OF REGULATORY REQUIREMENT OF mRNA BASED THERAPEUTICS AS PER CDSCO:

mRNA (messenger RNA) products are medicine which contain mRNA, designed to provide cells with instructions. mRNA is single stranded ribonucleic acid which carries codding information for protein synthesis. mRNA based therapeutics are used in cancer immunotherapy, vaccines and treatment of infectious diseases.

In India**,** mRNA-based vaccines are regulated as new drug products**.** The regulatory pathway requires evaluation of quality, efficacy, safety, manufacturing, and post-approval safety**.** The legal frame work of CDSCO provides rules required to regulate biological products and drugs the main legal framework for mRNA therapeutics are:

- Drugs and Cosmetics Act 1930
- Drugs and Cosmetics Rules ,1945
- And Recent one New Drugs and Clinical Trails Rules ,2019

The legal frame work sets the standard and requirement that the manufacturer should follow and provides procedure for approval. the aim is to ensure safety of medicines and protect patient from unsafe products

The mRNA vaccines/products need to satisfy the quality criteria. the impurities such as protein should be limited. the manufacturing procedure of mRNA vaccine should comply with good manufacturing practice (GMP) guideline to ensure safety of products.

Regulatory Approval:

In India, mRNA therapeutics are regulated by the Central Drugs Standard Control Organization (CDSCO), an organization that operates under the Ministry of Health and Family Welfare. The entity responsible for regulation of the therapy is the Drugs Controller General of India (DCGI). mRNA therapies are typically regarded as biological products according to Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945.

Firstly, there are preclinical studies that aim at demonstrating pharmacological activity, safety, immunogenicity, and toxicity; particular attention is paid to stability of the mRNA molecule and LNP. After successful completion of preclinical studies, sponsors need to get CDSCO and registered Ethics Committee approval to conduct clinical trials. Clinical trials of mRNA-based therapies typically include three phases in order to test safety, dosing, and effectiveness of the product.

Once the product is successfully developed in the course of clinical trials, New Drug Application (NDA) needs to be submitted to CDSCO in the Common Technical Document (CTD) format. The documents include data on manufacturing, quality control, preclinical and clinical studies. It is necessary to mention that in case of mRNA-based therapies CMC data becomes particularly relevant because it directly effects on the quality and performance of the product[9].

Marketing authorization cannot be granted until the quality, safety, and efficacy of the product have been assessed by CDSCO. Besides, GMP requirements described in Schedule M are to be

followed; in other words, appropriate controls are to be developed for each stage of production, from mRNA synthesis and purification to formulation, storage, and batch testing of the product.

Furthermore, in case if the disease or situation that the product is going to handle is severe or urgent, CDSCO can consider accelerated or emergency approval. After obtaining marketing authorization, manufactures have to implement pharmacovigilance and ensure safety of the product by reporting adverse drug reactions, Periodic Safety Update Reports (PSURs), and conducting additional post-marketing studies.

Thus, the approach to regulating of mRNA therapies in India is step-by-step; the quality, safety, and efficacy of mRNA-based therapies are ensured throughout the preclinical development, clinical trials, manufacturing, marketing authorization, and post-marketing surveillance.

Overview of Swissmedic:

The Swiss Agency for Therapeutic Products is the national regulatory authority responsible for the regulation of medicines and medical devices in Switzerland. It was establishes on January 1st 2002. The headquarter is located at Bern, Switzerland. The medicinal products need approval from swissmedic to be marketed. The goal is to protect health.

Objective of Swissmedic:

The main objectives of SWISSMEDIC is to promote public health by ensuring safer medicinal products. Swiss agency for therapeutic products reviews medical devices, medicinal and therapeutic product, it monitors medicine after approval and marketing for safer side. They encourage innovation of new drugs; they also safeguard the veterinary medicines.

The responsibility of SWISSMEDIC are

- Ensure the quality of medicinal product
- Monitor safety of medicine
- Protect patient from unsafe therapeutic products

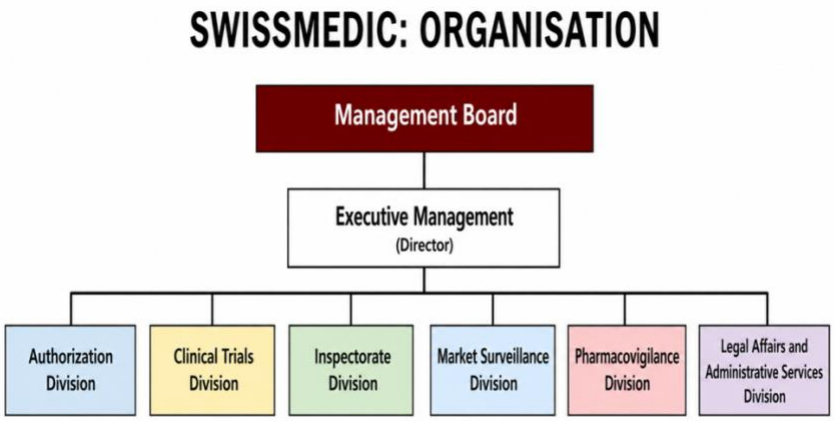

Figure 4: Organization of Swissmedic

Swissmedic, the Swiss agency of therapeutic products is linked with federal department of home affairs. The agency council of swissmedic govern performance and management of swissmedic and the executive management then oversees day to day operations. Executive board reports all documents to the management board and to swissmedic to ensure all the procedure are carried out legally. Under the management board there are seven divisions. where each division perform separate function to deliver safer therapeutic products.

Overview of Regulatory Requirement For mRNA Based Therapeutics As Per Swissmedic:

In Switzerland the mRNA-based products are regulated as medicinal product under the advanced therapy medicinal product (ATMP) framework[10]. Swissmedic regulates medicinal products, including vaccines. For an mRNA-based therapeutic, the regulatory requirements focus on quality of the product, safety, efficacy, manufacturing, and post marketing changes. Swissmedic review the submitted documents before granting market approval. The member for Swiss agency appointed by Federal Council.

The legal framework of swissmedic provides rules required to regulate biological products and drugs, the main import and framework are

- Therapeutic Products Act, (TPA)
- Human Research Act[5]
- Clinical Trials Ordinance(clinO)
- Regulation for Advanced therapy medicinal product (ATMPs)

The above-mentioned frameworks provide detailed requirements for clinical trials and manufacturing procedure. The quality of the mRNA based medicinal products should be maintained as per regulatory, Manufacturing must be complied with the GMP requirement.

Regulatory Approval:

In Switzerland, mRNA-based therapeutics are regulated by Swissmedic, the Swiss Agency for Therapeutic Products, under the Therapeutic Products Act (TPA) and the Medicinal Products Licensing Ordinance (MPLO). Depending on their characteristics, these products may be regulated as biological medicinal products or may fall within the category of Advanced Therapy Medicinal Products (ATMPs). Swissmedic evaluates their quality, safety, and efficacy before marketing authorization is granted.

The regulatory process begins with preclinical development**,** during which laboratory and animal studies are conducted to evaluate pharmacological activity, biological effects, toxicity, and potential risks. Particular attention is given to the stability of the mRNA molecule and the lipid

nanoparticle (LNP) delivery system. The data generated during this stage support the transition to clinical development.

Before human clinical trials can begin, the sponsor must obtain authorization from Swissmedic and approval from the relevant ethics committee. Clinical trials are done in three phases. Phase I primarily evaluates safety and appropriate dosage, Phase II examines efficacy and continued safety in a larger group, and Phase III confirms safety and efficacy in a larger patient population[6].

After successful clinical development, the manufacturer submits a Marketing Authorization Application (MAA) to Swissmedic, generally using the Common Technical Document (CTD) format. The dossier includes information on manufacturing processes, quality control, non-clinical studies, and clinical trial results. For mRNA therapeutics, detailed Chemistry, Manufacturing and Controls (CMC) data are particularly important because the quality and consistency of the mRNA sequence and LNP formulation can directly affect product performance.

Swissmedic conducts a scientific evaluation based on three key parameters: quality, safety, and efficacy. The quality assessment examines manufacturing consistency, purity, potency, and stability. Safety evaluation includes the review of toxicological and clinical safety data, adverse reactions, and immune responses. Efficacy is assessed using clinical trial data to determine whether the therapeutic provides meaningful benefits to patients. Marketing authorization is granted when the overall benefits are considered to outweigh the potential risks.

Manufacturers must also follow with Good Manufacturing Practice (GMP) requirements. Production steps, including mRNA synthesis, purification, LNP formulation, filling, packaging, and batch release, must be properly controlled and validated. Stability studies and appropriate storage and transportation conditions are particularly important because mRNA products are sensitive to degradation.

Switzerland also provides mechanisms to facilitate the availability of innovative medicines. Under Article 13 of the Therapeutic Products Act, Swissmedic may take into account evaluations conducted by recognized foreign regulatory authorities, such as the EMA and FDA, during its assessment process.

Overall, the Swiss regulatory pathway provides a structured approach for the development and approval of mRNA-based therapeutics, covering preclinical evaluation, clinical trials, marketing authorization, manufacturing controls, and post-approval regulatory requirements.

Comparative Analysis of Regulatory Requirement For mRNA Based Therapeutics Between CDSCO and SWISSMEDIC:

Table 1: Comparative analysis of regulatory requirement

No.	Parameter	India (CDSCO)	Switzerland (Swissmedic)
1	Regulatory authority	CDSCO	Swissmedic
2	Regulatory framework	No specific framework for mRNA; considered as new drug	Specific framework for advanced therapy medicinal products (ATMPs)
3	Governing body	Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services	Federal Department of Home Affairs (FDHA), Swiss Government
4	Head	Drugs Controller General of India (DCGI)	Executive Director
5	International collaboration	Collaborates with WHO and other international regulatory authorities	Effective collaboration with foreign and international regulatory authorities
6	Example	GEMCOVAC-OM (Gennova) – COVID-19 mRNA vaccine	mRESVIA(Moderna) –RSV mRNA vaccine
7	Transparency	publicly available only limited assessment reports	Greater transparency to public
8	Regulatory timeline	Approximately 12–18 months	Approximately 10–18 months
9	Emergency use authorization	Available during public health emergency	Not provided as a separate emergency-use pathway
10	Post market surveillance	Mandatory ADR reporting	Mandatory safety monitoring
11	Legal framework	New drug and clinical trial rules 2019	Therapeutic Products Act (TPA) and Human Research Act (HRA)
12	Reference standards	Indian Pharmacopoeia (IP)	European Pharmacopoeia
13	Import requirement	Import license and CDSCO approval	Swissmedic import authorization required

Overview of Import Export and Sales of mRNA Therapeutics According to Regulations of CDSCO and SWISSMEDIC:

mRNA-based treatments need special rules for moving them between countries and selling them because they are considered advanced biologicals or gene-based medicines. They also need careful handling to keep them cool and have unique safety concerns that must be managed.

This comparison explains how India's Central Drugs Standard Control Organization (CDSCO) and Switzerland's Swissmedic handle the import, export, and selling of mRNA products.

Key Regulatory framework

Table 2: Comparative table of regulations of CDSCO and Swissmedic

Regulatory Aspect	India (CDSCO)	Switzerland (Swissmedic)
Primary Legislation	New Drugs and Clinical Trials Rules (NDCTR 2019) under the Drugs and Cosmetics Act.	Therapeutic Products Act (TPA) and Medicinal Products Licensing Ordinance (MPLO).
Product Classification	Biological / "New Drug" (or Gene Therapy	Advanced Therapy Medicinal Product (ATMP)

	product)	or Biological/Vaccine
Primary Portal / Platform	SUGAM Portal & NSIWS	eCTD Platform & NDS-WEB
International Alignment	Partial alignment with WHO / ICH	Fully compliant with ICH and PIC/S standards, with strong alignment to EMA and US FDA guidelines.

Import Regulations:

India (CDSCO):

1. **Import License (Form 10):** An import license, Form 10, is needed for foreign manufacturing sites that make mRNA treatments. Before getting this license, these sites must first register their facility with CDSCO using Form 41. An authorized agent from India files from 10 to process customs clearance[7].
2. **Clinical Data Requirements**: Clinical data requirements state that global clinical data should be supported by local clinical trials or local phase III waivers granted by the Subject Expert Committee (SEC) according to CDSCO guidelines.
3. **Cold-Chain Clearance:** Port officials check the temperature records of ultra-cold mRNA shipments at specific entry points like Mumbai, Delhi, and Bengaluru before allowing them to be released[8].

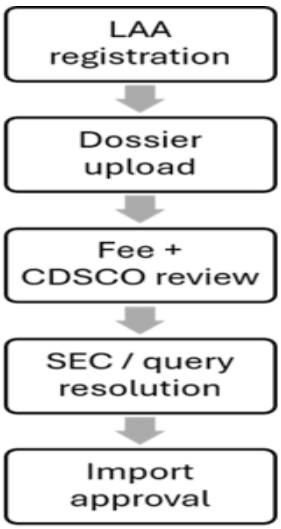

Figure 5: Flowchart of Import in CDSCO

Switzerland (Swissmedic):

1. **Establishment License (Import):** To import biological products, the importer needs a license from Swissmedic that allows them to do the import.
2. **Batch Release & Testing:** Each batch that is imported needs to be checked and approved by a Responsible Person (RP) who is certified under Swiss Good Manufacturing Practice

(GMP) or European/PIC/S mutual recognition agreements. This approval process is called batch release and testing.

3. **Reliance & Accelerated Pathways:** Swissmedic leverages review reliance models (fast-tracking products already authorized by FDA or EMA), provided Swiss-specific Module 1 requirements are met.

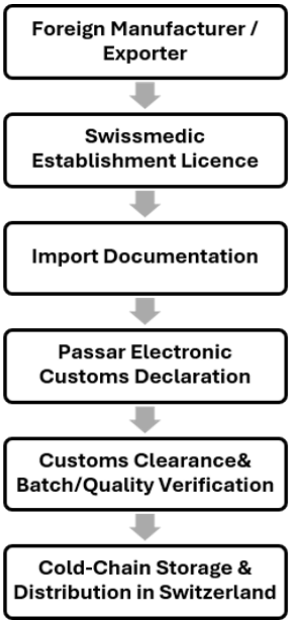

Figure 6: Flowchart of Import in Swissmedic

Commercial Sale and Market Access:

India (CDSCO):

Retail/Wholesale Licensing:

To distribute mRNA therapeutics, you need Form 20/21 licenses that are given by the State Licensing Authorities. Distributors need to have confirmed ultra-deep cold storage spaces that can keep things at temperatures between -80°C and -20°C.

Price Compliance:

The cost of medicines sold commercially might be checked by India's National Pharmaceutical Pricing Authority (NPPA) to ensure they are set at the right price.

Switzerland (Swissmedic & FOPH)

Market Authorization (MA):

Market Authorization (MA) is given by Swissmedic once they have checked the quality, safety, and effectiveness of the product[11].

Reimbursement Approval:

Swissmedic's authorization lets the product be sold commercially, but to be covered by mandatory health insurance, a separate application must be submitted to the Federal Office of Public Health (FOPH).

Multilingual Labeling:

Packaging and the information leaflets for patients need to be written in German, French, and Italian.

Export Regulations:

India (CDSCO):

No Objection Certificate (NOC):

To export mRNA products that are not approved or are specialized, made in India, you need an Export No Objection Certificate (NOC) from CDSCO.

Manufacturing License (Form 25/28):

Manufacturing License (Form 25/28): Local contract development and manufacturing organizations (CDMOs) that make mRNA for export need to have a valid approval from a state licensing authority, which must be approved by CDSCO.

SWITZERLAND (SWISSMEDIC):

Manufacturing License (Form 25/28):

Companies that buy or sell mRNA treatments outside Switzerland, including those that bring products in for re-export, need a special Swissmedic license just for international trade.

Full Chain Traceability:

Exporters need to show they follow all the rules for good distribution practices from start to finish and keep full records that can track each batch throughout the whole supply chain. Swissmedic must be notified following export operations.

Overview of Market Analysis Of mRNA-Based Therapeutics In India and Switzerland:

Introduction:

mRNA-based therapeutics are innovative medicines that use messenger RNA to help treat or prevent diseases. The success of mRNA vaccines has increased interest in their use for cancer, infectious diseases, and genetic disorders. India and Switzerland are important markets with different strengths and opportunities in the development of mRNA therapeutics.

India mRNA-Based Therapeutics Market:

Market Overview:

The Indian mRNA therapeutics market is currently at an emerging stage but has strong potential for future growth. The growth of this market is supported by increasing investment in

biotechnology, expanding pharmaceutical research, growing healthcare needs, and government support.

The success of mRNA vaccines during the COVID-19 pandemic increased interest in using this technology for other diseases. In India, important areas of research include infectious diseases, cancer, rare genetic disorders, and personalized medicine.

mRNA-based products in India are regulated under the framework for biological products by the **Central Drugs Standard Control Organization (CDSCO).**

India Market Segmentation:

Table 3: India market segments

Category	Major Segments
Product Type	mRNA vaccines, therapeutic mRNA drugs, personalized medicines, protein replacement therapies
Therapeutic Areas	Infectious diseases, cancer, rare genetic disorders, cardiovascular diseases
Delivery Technology	Lipid nanoparticles, polymer-based systems, liposomes and peptide-based systems
Development Stage	Preclinical research, clinical trials, commercialized products
Geographical Areas	North, South, East, West and Central India

Infectious diseases and vaccine development are important application areas in the Indian market. Lipid nanoparticle technology is also an important delivery system because of its use in mRNA vaccine development.

India Market Growth:

According to the information provided in the document, the Indian mRNA therapeutics market shows strong growth potential.

Table 4: Market growth in India

Parameter	Value
Market Size (2023)	USD 296 million
Projected Market Size (2030)	USD 1.02 billion
Expected Growth Rate	21.3% CAGR
Largest Application Area	Infectious diseases and vaccines
Fastest-Growing Opportunity	Cancer therapies and personalized vaccines

According to the information provided in the document, the Indian mRNA therapeutics market shows strong growth potential.

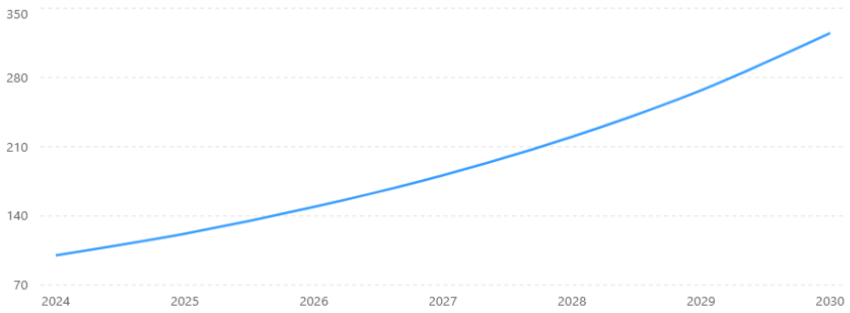

Figure 7: India mRNA Therapeutics Market Growth

India: Drivers, Challenges and Opportunities:

Table 5: Drivers, Challenges and Opportunities

Drivers	Challenges	Opportunities
Growing biotechnology industry	High research and manufacturing cost	Cancer treatment
Government support	Limited advanced infrastructure	Infectious disease vaccines
Strong pharmaceutical manufacturing	Cold-chain storage difficulties	Personalized medicine
Success of COVID-19 mRNA vaccines	Shortage of skilled experts	Cost-effective global manufacturing

Switzerland mRNA-Based Therapeutics Market:

Market Overview:

Switzerland has a strong and advanced pharmaceutical and biotechnology ecosystem. The country benefits from world-class research institutions, advanced manufacturing facilities, and the presence of major pharmaceutical companies.

The Swiss mRNA therapeutics market is supported by increasing investment in biotechnology and growing interest in precision medicine. Research is expanding into cancer, infectious diseases, rare genetic disorders, cardiovascular diseases, and regenerative medicine.

The regulatory authority responsible for therapeutic products in Switzerland is Swissmedic, the Swiss Agency for Therapeutic Products.

Switzerland is therefore considered an important European center for the development and commercialization of advanced mRNA-based therapies.

Switzerland Market Segmentation:

Table 6: Switzerland Market Segmentation

Category	Major Segments
Product Type	Prophylactic therapeutics, therapeutic vaccines, protein replacement therapies
Therapeutic Areas	Oncology, infectious diseases, genetic, cardiovascular and neurological disorders
Delivery Technology	Lipid nanoparticles, polymers, peptides, viral vector-assisted systems
Development Stage	Discovery, preclinical research, Phase I–III clinical trials
Major Regions	Zurich, Basel, Geneva, Lausanne/Vaud and Bern

Switzerland has a strong focus on advanced therapeutic research, particularly oncology, precision medicine, rare genetic disorders, and regenerative medicine.

Switzerland Market Growth:

The market information reported in the document is shown below.

Table :7 Switzerland Market Growth

Parameter	Value
Market Size (2023)	USD 296 million*
Projected Market Size (2030)	USD 1.02 billion*
Expected Growth Rate	21.3% CAGR*
Largest Application Area	Infectious diseases and vaccines
Major Growth Opportunity	Cancer therapies and personalized vaccines

The source document describes Switzerland as an important hub for mRNA innovation because of its strong pharmaceutical ecosystem and advanced biotechnology research

Switzerland: Drivers, Challenges and Opportunities

Table 8: Switzerland: Drivers, Challenges and Opportunities

Drivers	Challenges	Opportunities
Strong pharmaceutical industry	High development cost	Cancer therapies
Advanced research facilities	Complex manufacturing	Personalized medicine
Focus on precision medicine	Strict regulatory requirements	Rare genetic diseases
Strong industry–research collaboration	Limited long-term clinical data	Advanced mRNA technologies

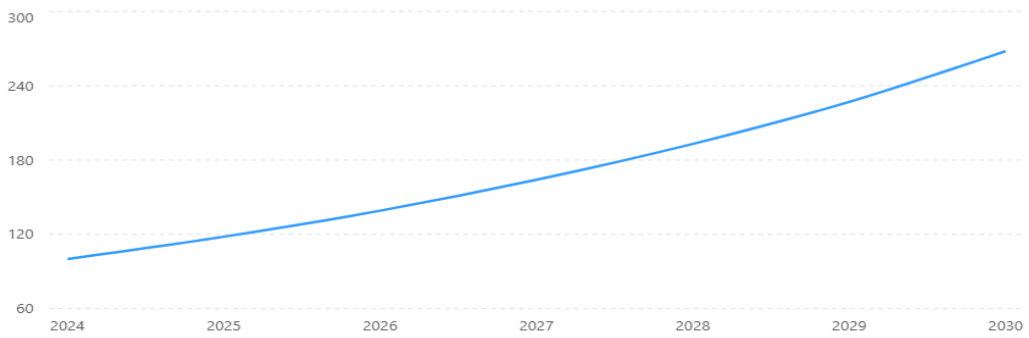

Figure 8: Switzerland mRNA Therapeutics Market Growth

Comparative Analysis: India vs Switzerland

The following table provides a clear comparison between the two countries.

Table 9: Comparative Analysis: India vs Switzerland

Factor	India	Switzerland
Market Position	Emerging market	Advanced market
Regulatory Authority	CDSCO	Swissmedic
Pharmaceutical Strength	Strong manufacturing industry	Strong research and innovation
Main Advantage	Cost-effective production	Advanced technology
Research Infrastructure	Rapidly expanding	Highly developed
Major Focus Areas	Vaccines, infectious diseases, cancer	Oncology, precision medicine, rare diseases
Manufacturing Potential	High and cost-effective	Advanced and high-quality
Major Challenge	Infrastructure and cold-chain limitations	High cost and complex development
Growth Opportunity	Global manufacturing and affordable therapies	Advanced therapeutic innovation
Key Industry Players	Gennova, Serum Institute, Bharat Biotech, Zydus	Roche, Novartis, Lonza, Moderna

Overview of Recent Amendment and Advancement In India:

India has seen some new regulatory steps that make it easier to build mRNA vaccines and treatments. One key change came in 2026, with an update to Rule 52 in the NDCTR, 2019**.** This update added a prior intimation process for making some new drugs, including investigational new drugs. The goal is for analytical work and non-clinical testing. With this method, a firm can start certain listed actions after it submits a prior notice to the Central Licensing Authority and receives an acknowledgement. It does not require waiting for the full permission step. The expectation is that this will ease the regulatory load and help research and development move sooner. The update also cut the legal time for processing some test licenses. The window went from 90 days down to 45 days.

A second factor is that the NDCTR, 2019 is still being used as the main rule set. It covers new drugs, clinical trials, and investigational products in India. Changes made recently have aimed at simpler procedures and fewer slowdowns. These points matter for mRNA products. That is because the work usually runs through preclinical studies, then clinical trials. It also needs specialized manufacturing.

There is also the Biological Products Guidance, Version 1.2, dated 2024. This guidance strengthens requirements for product quality. It focuses on how manufacturing is controlled and how stability, safety, and efficacy are handled. mRNA products are not simple items. They are complex biological products. So, developers need solid control of the manufacturing process. They also need a careful look at critical quality attributes. Stability work needs extra focus. India saw a big step forward when it approved mRNA vaccines made in the country. The approvals covered GEMCOVAC-19 and GEMCOVAC-OM. This showed that India can build mRNA vaccine work and also oversee it under the rules that already apply to biological products. It also sets a foundation for new mRNA vaccine efforts and for mRNA therapies that may come later. In general, recent rule changes and other regulatory updates have made the system feel more open to new drug ideas. Some steps have been made easier, review times can be shorter, and guidance has improved. Even so, India does not yet have a stand -alone set of rules made just for mRNA treatments. Still, the current rules for biological products and clinical trials can support how these products are built and tested. As mRNA work grows, moving from vaccines into fields like cancer, infections, and genetic conditions, India may later add more focused guidance for mRNA. That future guidance would need to cover quality, safety, and how well these products work.

Overview of Recent Amendment and Advancement In Switzerland:

Recent amendments and advancements by Swissmedic have helped in supporting the development of mRNA-based therapeutics in Switzerland. As mRNA technology is growing rapidly and is being used not only for vaccines but also for diseases such as cancer, infectious diseases, and genetic disorders, there is a need for proper regulatory support to ensure the safety, quality, and effectiveness of these products.

The recent amendments have mainly focused on improving clinical trial requirements, patient safety, transparency, and regulatory oversight. The revision of the Human Research Ordinances has strengthened the protection of clinical trial participants and improved the monitoring of innovative therapies, including mRNA-based products. Similarly, increased transparency requirements have made it necessary for sponsors to provide better information about clinical trials and their outcomes.

The new rules also seek to strengthen how studies are supervised. They add more openness about how clinical research is carried out. A further change is the Fast-Track Pilot Project for clinical trials. It started on 1 July 2025. The goal is to shorten the time it takes to process some clinical trial filings. The pilot is meant for treatments that meet a high medical need. It also covers investigational medicinal products that were already assessed by Swissmedic in earlier trials. In this pilot, some files may be handled in 20 days instead of 30. Other files may take 40 days instead of 60. This can speed up work on new and promising therapies[4]. Still, the fast-track path only covers certain first clinical trial applications. It does not cover every innovative product on its own. Swissmedic has also revised how it handles innovative and advanced therapies. In its rules, nucleic acid products are treated as part of the wider field of advanced therapeutic products. This includes mRNA products and mRNA vaccines. Swissmedic uses a risk-based method for these kinds of therapies. The aim is a regulatory setup that helps them move forward. At the same time, it should keep safety and quality requirements in place. The Swissmedic Innovation Office offers a way to speak early with the regulator. Developers of innovative medicinal products can seek regulatory input before later steps. Early talks can help teams figure out what rules may apply during development. This also includes planning for clinical trials and later authorization. Taken together, the recent updates in Switzerland support innovative therapies more than before. This includes therapies based on mRNA. The changes to the Human Research Ordinances improve protection for people taking part. They also make the rules clearer and easier to track. At the same time, the fast track option for clinical trials can cut some waiting time during development. The new support for innovation in the rules is meant to help researchers move without skipping safety steps. Overall, Switzerland tries to balance firm oversight with help for new science, so that mRNA treatments can be developed in a way that is safe, effective, and high quality.

CONCLUSION:

mRNA-based medicines represent a promising advancement in modern therapeutics, particularly because they provide cells with temporary instructions to produce specific proteins without permanently altering the patient's DNA. The successful development and use of mRNA vaccines have demonstrated the practical potential of this technology, while applications in cancer treatment and genetic disorders continue to be investigated. However, challenges related to delivery, molecular stability, storage, immune responses, and large-scale manufacturing remain important barriers to wider clinical application.

In India, mRNA-based products are regulated through the existing drug and clinical trial framework under the Central Drugs Standard Control Organization (CDSCO), while developments

such as the GEMCOVAC vaccine demonstrate the country's growing capacity for indigenous mRNA research and manufacturing. Recent regulatory developments may further support innovation and development in this field. Switzerland, through Swissmedic, has a more established regulatory environment for advanced and innovative therapies, providing structured pathways for their evaluation.

Overall, both India and Switzerland have important strengths in the development of mRNA-based medicines. India has considerable potential in cost-effective manufacturing, large-scale production, and expanding domestic research capabilities, while Switzerland benefits from an established regulatory and research ecosystem. Continued advances in mRNA design, delivery technologies, manufacturing, and regulatory frameworks will be essential for translating the promise of mRNA therapeutics into safe, effective, and widely accessible medicines.

ACKNOWLEDGEMENT:

It is a matter of honor for us to convey our sincerest thanks to Dr. P. Ashok Kumar, Professor, Department of Pharmaceutical Regulatory Science, Sree Siddaganga College of Pharmacy, Tumkur, India, whose assistance, encouragement, and support have enabled us to complete this work. We also convey our thanks to the management, faculty members, and other staff members of the Sree Siddaganga College of Pharmacy for their support and for providing the necessary facilities for this work. Lastly, we are grateful to all those people who have been instrumental in the completion of this article.

REFERENCES:

1. National Library of Medicine (US), National Institutes of Health. mRNA therapeutics [Internet]. Bethesda (MD): National Institutes of Health; 2023 [cited 2025 May 24]. Available from: https://ncbi.nlm.nih.gov
2. National Center for Biotechnology Information (US). NCBI [Internet]. Bethesda (MD): National Library of Medicine; [cited 2025 May 24]. Available from: https://www.ncbi.nlm.nih.gov
3. PubMed Central (US), National Library of Medicine. PubMed Central [Internet]. Bethesda (MD): National Institutes of Health; [cited 2025 May 24]. Available from: https://www.ncbi.nlm.nih.gov/pmc/
4. Swissmedic. New regulatory provisions from 1 November 2024 [Internet]. Bern: Swissmedic; 2024 [cited 2025 May 24]. Available from: https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/neues-verordnungsrecht-ab-1-nov-2024.html

5. Swissmedic. Revised regulatory provisions concerning the Human Research Act [Internet]. Bern: Swissmedic; [cited 2025 May 24]. Available from: https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/klv-revidiertes-verordnungsrecht-humanforschungsgesetz.html
6. Swissmedic. Implementation of regulatory provisions for clinical trials on medicinal products [Internet]. Bern: Swissmedic; [cited 2025 May 24]. Available from: https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/clinical-trials/clinical-trials-on-medicinal-products/implementierung-verordnungsrecht.html
7. Central Drugs Standard Control Organization. Imports [Internet]. New Delhi: Government of India; [cited 2025 May 24]. Available from: https://cdsco.gov.in/opencms/opencms/en/Departments/Headquarters/imports
8. Central Drugs Standard Control Organization. Guidance document: cold chain compliance [Internet]. New Delhi: Government of India; [cited 2025 May 24]. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/Guidance_doc
9. Central Drugs Standard Control Organization. Vaccines: regulatory compliances [Internet]. New Delhi: Government of India; [cited 2025 May 24]. Available from: https://cdsco.gov.in/opencms/opencms/en/biologicals/Vaccines
10. Swissmedic. Advanced therapy medicinal products (ATMPs) [Internet]. Bern: Swissmedic; [cited 2025 May 24]. Available from: https://www.swissmedic.ch/swissmedic/en/home.html
11. Swissmedic. Market authorization [Internet]. Bern: Swissmedic; [cited 2025 May 24]. Available from: https://www.swissmedic.ch/swissmedic/en/home.html