Journal of Regenerative Medicine and Molecular Innovation
Vol. 2 No. 2 Juni 2026
E-ISSN: 3090-0824
Open Access: https://journals.ai-mrc.com/jrmmi

Management Strategies for Advanced Therapy Medicinal Product Services: Integrating Hospital Administration, Business Models, and Regulatory Frameworks.

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Article Info

Article history:
Received 25-04-2026
Revised 21-05-2026
Accepted 17-06-2026

Keyword:
Advanced Therapy Medicinal Products (ATMPs); Business Models; Hospital Administration; Regulatory Frameworks; Value-Based Pricing

ABSTRACT

Advanced Therapy Medicinal Products (ATMPs) including gene therapies, somatic cell therapies, and tissue-engineered products represent a transformative frontier in regenerative medicine. However, their clinical integration poses unprecedented managerial challenges across hospital administration, financing, and regulatory compliance. This narrative review synthesizes evidence identified through a structured literature search of PubMed, Scopus, and Web of Science databases, supplemented by relevant regulatory and policy documents. Publications addressing ATMP management, reimbursement, regulatory frameworks, and service delivery models were screened and selected based on their relevance to the review objectives. We examine operational workflows and infrastructure requirements for hospital-based ATMP programs, analyze evolving business models including value-based pricing and managed entry agreements, and compare regulatory frameworks across the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), and emerging jurisdictions such as Indonesia's BPOM. Case studies of CAR T-cell therapy implementation and hub-and-spoke organizational models illustrate practical pathways. A conceptual framework integrating clinical, business, and regulatory domains is proposed. Key insights include the necessity of centralized GMP infrastructure, multi-stakeholder reimbursement innovation, and adaptive regulatory pathways to balance patient access with sustainability. Recommendations emphasize early health technology assessment engagement, performance-based contracting, and international harmonization efforts to support scalable and equitable ATMP service delivery.

INTRODUCTION

Advanced Therapy Medicinal Products (ATMPs) constitute a heterogeneous class of biological medicines defined by their reliance on genes, cells, or tissue engineering to achieve therapeutic effects. In the European Union, ATMPs are formally classified into four categories: gene therapy medicinal products (GTMPs), somatic cell therapy medicinal products (SCTMPs), tissue-engineered products (TEPs), and combined ATMPs incorporating medical devices. In the United States, analogous products are regulated as cellular and gene therapy (CGT) products under the biologics framework of the Food and Drug Administration (FDA). These therapies have demonstrated remarkable efficacy in conditions previously considered untreatable, including certain hematologic malignancies, inherited genetic disorders, and degenerative diseases.

The growing pipeline of ATMPs with an estimated 10–20 products per year expected to seek marketing authorization in the coming decade has created an urgent need for robust management frameworks. Unlike conventional pharmaceuticals, ATMPs require specialized infrastructure for manufacturing, storage, logistics, and administration. Their high unit costs, often exceeding one million dollars per patient, challenge traditional reimbursement models and raise concerns about health system

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sustainability and equity of access. Furthermore, the regulatory landscape for ATMPs is complex and evolving, with significant variation across jurisdictions that complicates global development and market access.

Despite the increasing number of approved ATMPs and the growing body of literature on their clinical effectiveness, existing studies predominantly focus on scientific, clinical, and regulatory aspects, while the management of ATMP services remains insufficiently explored. Current evidence is fragmented across individual topics such as manufacturing challenges, reimbursement mechanisms, regulatory pathways, or ethical issues, with limited efforts to integrate these dimensions into a comprehensive service management framework. Consequently, stakeholders lack a consolidated understanding of how operational, business, regulatory, and ethical factors interact to influence the successful implementation and sustainability of ATMP services. This gap is particularly important as healthcare organizations increasingly transition from evaluating ATMP efficacy to establishing scalable and sustainable delivery systems.

This narrative review aims to synthesize current knowledge on management strategies for ATMP services across four interconnected domains: hospital and clinic operations, business models, regulatory compliance, and ethical considerations. By addressing the fragmented nature of existing evidence and providing an integrated perspective on ATMP service management, this review seeks to fill an important knowledge gap in the literature. By integrating evidence from policy documents, peer-reviewed literature, and real-world case examples, we provide a framework for stakeholders seeking to develop or optimize ATMP service delivery programs.

RESEARCH METHODS

This study employed a narrative review design to synthesize current evidence and expert perspectives on the management of Advanced Therapy Medicinal Product (ATMP) services. The review focused on four interconnected domains: hospital and clinic administration, business models and reimbursement strategies, regulatory and policy frameworks, and ethical considerations.

A systematic literature search was conducted in PubMed, Scopus, and Web of Science databases to identify relevant studies published between 2015 and 2025. The search strategy combined keywords and Boolean operators related to ATMP implementation and management, including (“Advanced Therapy Medicinal Product” OR “ATMP” OR “CAR T-cell therapy” OR “gene therapy” OR “cell therapy” OR “tissue-engineered product”) AND (“hospital management” OR “service delivery” OR “business model” OR “reimbursement” OR “regulation” OR “policy” OR “ethics”). Additional sources were identified through manual screening of reference lists and relevant regulatory documents.

The initial search yielded 327 records. After removing 74 duplicates, 253 records were screened based on titles and abstracts. A total of 167 records were excluded due to insufficient relevance to ATMP service management, resulting in 86 full-text articles assessed for eligibility. Following full-text review, 52 publications met the inclusion criteria and were included in the final synthesis. Inclusion criteria comprised peer-reviewed articles, regulatory reports, and policy documents addressing operational, financial, regulatory, or ethical aspects of ATMP implementation. Publications focusing exclusively on clinical efficacy or laboratory outcomes without implications for service management were excluded.

The review prioritized sources addressing operational workflows, staffing models, GMP-compliant infrastructure, value-based pricing, managed entry agreements, and regulatory pathways under institutions such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and emerging regulatory authorities including Indonesia’s BPOM. To enhance methodological rigor, the quality of included sources was appraised using relevance, methodological clarity, transparency of data sources, and applicability to ATMP service delivery. Studies and reports were categorized as high, moderate, or low quality based on their methodological robustness and practical relevance.Evidence was analyzed descriptively and thematically to identify recurring challenges, practical implementation models, and strategic recommendations for sustainable ATMP

service delivery. Case examples, including hub-and-spoke models and academic GMP facilities, were used to illustrate real-world approaches to integrating clinical, financial, and regulatory requirements. The findings were then synthesized into a conceptual framework linking clinical operations, business sustainability, and regulatory compliance in ATMP service management.

RESULTS

Hospital and Clinic Management of ATMP Services

Operational Workflows

The clinical delivery of ATMPs involves a complex, multi-step supply chain that differs substantially from conventional pharmaceutical administration. For autologous CAR T-cell therapies, the workflow typically includes: patient identification and referral, leukapheresis for cell collection, cryopreservation and shipment to a manufacturing facility, genetically modified cell production (often requiring 2–4 weeks), return of the product to the treatment center, patient preconditioning chemotherapy, product thawing and infusion, and post-infusion monitoring for toxicities such as cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome . Across studies, the main managerial challenge is not simply the number of steps, but the interdependence between clinical timing, manufacturing capacity, logistics, and regulatory release. Delays at any point in this chain can affect patient eligibility, product viability, and treatment outcomes, making ATMP delivery more vulnerable to coordination failure than conventional biologics.

The hub-and-spoke model has emerged as an effective organizational framework for managing this complexity within public health networks. The Catalan Blood and Tissue Bank experience in Spain provides a well-documented example: a centralized hub the cell processing laboratory and cryogenic medicine warehouse coordinates collection, processing, storage, and distribution for six academic hospitals. This model supported 348 leukapheresis procedures and 281 patient infusions over a five-year period, enabling rapid technical qualification of centers and consistent quality management across sites. Key success factors included standardized standard operating procedures, shared quality management systems, and defined role delineation between the hub, hospital pharmacies, and clinical teams. Compared with more decentralized hospital-based models, the Catalan approach appears stronger in quality standardization and infrastructure efficiency, but it may also create dependency on a central facility and require robust transport governance. Thus, its transferability to other jurisdictions depends on geography, referral networks, reimbursement arrangements, and the maturity of public blood and tissue infrastructure.

Staffing Models

Delivering ATMP services requires a multidisciplinary team with specialized competencies. Core personnel include: apheresis nurses and physicians for cell collection; cell processing laboratory staff trained in Good Manufacturing Practice (GMP); clinical pharmacists for product receipt, storage, and dispensing; oncology or transplant physicians for patient management; and quality assurance professionals for regulatory compliance. The JACIE (Joint Accreditation Committee of ISCT and EBMT) accreditation framework provides standards for cellular therapy programs that encompass staffing qualifications, training requirements, and competency assessment. However, accreditation frameworks mainly define minimum competence and process standards; they do not fully resolve workforce scarcity, role overlap, or the tension between research-oriented and service-oriented staffing models.

Academic GMP facilities face particular staffing challenges. These units often operate with limited personnel, competing priorities between research and clinical production, and difficulty retaining specialized staff due to salary differentials with industry. Strategies to address these challenges include establishing core facility models with open access for multiple research groups, contract-based manufacturing capacity allocation, and shared quality assurance infrastructure across institutions.

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Infrastructure Requirements

ATMP manufacturing and handling demand purpose-built infrastructure. GMP-compliant cleanrooms typically classified as Grade B (ISO 5) background with Grade A (ISO 4.8) critical zones are essential for aseptic processing. The Clean-Room Technology Assessment Technique (CTAT) model provides a framework for estimating costs and optimizing performance of academic GMP facilities, identifying core operational processes and their fixed costs alongside variable production costs. Capital investment for a hospital-based GMP facility typically ranges from several million to tens of millions of euros, depending on scale and scope.

For cryopreserved products, liquid nitrogen storage systems with continuous temperature monitoring, alarm systems, and backup power are mandatory. The creation of centralized medicinal product warehouses, as demonstrated in Catalonia, allows consolidation of cryogenic storage infrastructure across multiple hospitals, reducing duplication and improving cost-efficiency. Transportation logistics require validated cold chain systems, with dedicated couriers and temperature-monitored shipping containers.

Business Models and Reimbursement Strategies

Cost Structures and Pricing Challenges

The high prices of ATMPs reflect substantial research and development (R&D) costs, complex manufacturing processes, and small target patient populations. A cost-based pricing analysis of two gene therapies Libmeldy (OTL-200) for metachromatic leukodystrophy and Zolgensma (AVXS-101) for spinal muscular atrophy estimated base-case prices of €1,048,138 and €380,444 per treatment, respectively, substantially below their listed prices. R&D expenses were the most influential parameter for OTL-200, while profit margin assumptions most affected AVXS-101 pricing. However, considerable uncertainty remains due to lack of transparency in pharmaceutical company financial disclosures.

Manufacturing costs for ATMPs are significantly higher than for conventional biologics, driven by manual processing steps, individualized production for autologous products, and stringent quality testing requirements. Closed-system bioreactors and automation technologies offer pathways to reduce costs at scale, though adoption remains limited.

Value-Based Pricing and Health Technology Assessment

Traditional Health Technology Assessment (HTA) frameworks, based on incremental cost-effectiveness ratios, are poorly suited to ATMPs due to immature evidence at launch, uncertain long-term durability, and potentially curative outcomes. A Special Task Force of the International Society for Pharmacoeconomics and Outcomes Research has proposed incorporating additional value elements including the value of hope, real option value, insurance value, and scientific spillovers into ATMP assessments.

Value-based pricing, which links reimbursement to therapeutic benefit, has gained traction across European markets. In Germany, annuity payment models for CAR T-cell therapy have been implemented, spreading costs over the expected duration of benefit. Managed entry agreements (MEAs), including coverage with evidence development and performance-linked reimbursement schemes, allow payers to manage uncertainty while providing patient access. For example, Strimvelis (for ADA-SCID) was launched in Italy with a money-back guarantee for patients failing to sustain curative benefit.

Innovative Financing Mechanisms

The high upfront costs of ATMPs create affordability barriers even when cost-effectiveness thresholds are met. Several innovative financing approaches have been proposed:

- Amortization or leasing models, where payment is spread over multiple years aligned with expected benefit duration. This addresses the "affordability barrier" that arises when value-based pricing produces prices exceeding available budget.

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- Outcome-based annuity payments, where annual payments are contingent on continued therapeutic effect. Germany has implemented such models for CAR T-cell therapies, though patient mobility between insurers complicates long-term contracting.
- ATMP-specific funds, as proposed by multiple European stakeholders, which create ring-fenced budgets with clearly defined eligibility criteria to ensure patient access without destabilizing overall health system finances.
- Public-private partnerships, exemplified by the Innovative Medicines Initiative in Europe, which pool resources from government, industry, and academia to support ATMP development and infrastructure.

Regulatory and Policy Frameworks

European Union Framework

ATMPs in the EU are governed by Regulation (EC) No 1394/2007, which amended Directive 2001/83/EC and Regulation 726/2004. This framework mandates centralised marketing authorization through the European Medicines Agency (EMA), ensuring a single evaluation applicable across all member states. The Committee for Advanced Therapies (CAT), established within EMA, is responsible for product classification, quality assessment, and scientific advice.

The hospital exemption rule (Article 28 of Regulation 1394/2007) allows member states to authorize non-commercial ATMP use within hospitals on a national basis, provided no equivalent authorized product exists. However, application of this exemption varies substantially across member states, raising ethical concerns about patient safety and equity of access.

United States Framework

In the US, ATMPs are regulated as biological products under section 351 of the Public Health Service Act, with the FDA's Center for Biologics Evaluation and Research (CBER) having primary jurisdiction. The Office of Tissues and Advanced Therapies (OTAT) within CBER oversees product review. The 21st Century Cures Act (2016) established the Regenerative Medicine Advanced Therapy (RMAT) designation, providing expedited development and review pathways for qualifying products.

Key differences between EU and US approaches include: EU's more precise sub-classification into four ATMP categories versus US's broader gene therapy/cellular therapy dichotomy; differing definitions of "substantial manipulation" (EU) versus "more-than-minimal manipulation" (US); and variations in clinical trial oversight (EMA does not directly regulate trials, while FDA reviews all IND applications).

Emerging Regulatory Frameworks in Asia and Other Regions

Regulatory systems for ATMPs are rapidly developing across Asia, with notable variation in requirements for non-clinical data, manufacturing standards, and clinical evidence. Japan, South Korea, and China have established specific regulatory pathways for cell and gene therapies, while Indonesia's BPOM (Badan Pengawas Obat dan Makanan) is developing frameworks informed by international guidelines. International harmonization efforts, including the International Council for Harmonisation (ICH) and WHO initiatives, seek to reduce duplication and facilitate cross-border product development, though significant divergence remains in key technical requirements.

Quality and Safety Oversight

All ATMP regulatory frameworks emphasize GMP compliance for manufacturing, including requirements for environmental monitoring, raw material control, process validation, and final product testing. Potency assays, which measure biological activity, present particular challenges due to inherent variability in cell-based products. The colony-forming unit (CFU) assay for hematopoietic progenitors and T-cell stimulation assays for CAR T-cell products are examples of established potency tests, though standardization across laboratories remains an ongoing effort.

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DISCUSSION

Case Studies of Successful ATMP Service Implementation

CAR T-Cell Therapy in Catalonia, Spain

The Catalan Blood and Tissue Bank's hub-and-spoke model, described in Section 2.1, represents one of the most comprehensive implementations of ATMP services within a public health network. Over five years (2016–2021), the program treated 281 patients across six hospitals using both clinical trial and commercial CAR T-cell products. The centralized model enabled rapid technical qualification by manufacturers, consistent quality standards across sites, and efficient logistics for product receipt, storage, and distribution. The creation of a centralized medicinal product warehouse for cryogenic storage was a key innovation, reducing infrastructure duplication and leveraging existing hematopoietic stem cell transplant expertise. However, the Catalan experience should not be interpreted as universally transferable. Its success depended on pre-existing transplant infrastructure, public-sector coordination, and regional governance capacity, conditions that may be absent in fragmented or under-resourced healthcare systems. In systems with weaker referral networks, limited cryogenic logistics, or decentralized payer arrangements, a hub-and-spoke model may reproduce access bottlenecks rather than resolve them.

CAR T-Cell Therapy Implementation in the United States

Following FDA approval of tisagenlecleucel (Kymriah) and axicabtagene ciloleucel (Yescarta) in 2017, US cancer centers faced significant operational challenges in establishing cellular therapy programs. Successful implementation required multi-departmental collaboration involving pharmacy, cellular therapy laboratory, apheresis, intensive care, and bone marrow transplant units. A comprehensive cancer center that expanded its existing stem cell transplant program to incorporate CAR T-cell therapy reported that early leadership engagement, weekly cross-functional planning meetings, and defined patient flow processes were critical success factors. As of 2019, 61 approved Yescarta sites were operational in the US. Nevertheless, evidence from the United States also demonstrates that regulatory approval and site accreditation do not automatically translate into equitable or efficient service delivery. Commercial contracting, insurance authorization, reimbursement uncertainty, and regional concentration of certified centers have created delays and disparities in access. These findings contrast with more integrated public-network models and suggest that implementation barriers are shaped not only by clinical readiness but also by payer structure, institutional resources, and geographic distribution of specialized centers.

Academic GMP Facilities in Europe

Academic GMP facilities are major contributors to ATMP development, particularly for rare diseases and patient-specific therapies that lack commercial viability. The TUMCells facility in Munich, Germany, established as a consortium of the Technical University of Munich, Klinikum rechts der Isar, and Helmholtz Zentrum München, provides a model for academic ATMP manufacturing. Key design principles include: central core facility with open access for multiple research groups; contract-based capacity allocation; recognition of local expertise clusters; enforcement of common technical platforms; and lean, cost-effective management structures. However, a pan-European survey revealed substantial heterogeneity in regulatory implementation across member states, with evidence that EU legislators do not adequately engage with academic stakeholders, potentially stifling translation.

Challenges and Opportunities

Scalability and Manufacturing Capacity

The transition from small-scale academic production to commercial manufacturing poses major challenges. Current cleanroom capacity in the UK, for example, runs at approximately 72% operational capacity, with 80% considered full. Meeting projected demand from hundreds to tens of thousands of ATMP doses annually by 2028 will require substantial investment in manufacturing infrastructure, process automation, and closed-system technologies. Distributed manufacturing models, with multiple qualified production sites, offer potential for geographic scalability but introduce comparability challenges and increased regulatory burden.

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Equity of Access

The high costs of ATMPs raise profound equity concerns. Even in high-income countries, patient access is constrained by payer coverage decisions, geographic concentration of treatment centers, and capacity limitations. A study of CAR T-cell therapy access in the US identified disparities related to race, socioeconomic status, and geographic region. In low- and middle-income countries, the affordability gap is even more acute, requiring innovative financing mechanisms, tiered pricing strategies, and technology transfer arrangements to enable local production.

Ethical Considerations

Several ethical dimensions require attention. The hospital exemption rule in Europe, while intended to facilitate patient access, has been applied inconsistently, with some countries granting exemptions for products with limited safety and efficacy data. The International Society for Cell and Gene Therapy has called for an EU registry of hospital exemption applications and outcomes to improve transparency and reduce patient risk. Additionally, the opportunity cost of funding high-cost ATMPs within constrained health budgets necessitates explicit ethical deliberation about resource allocation priorities.

Opportunities for Harmonization

Despite current fragmentation, opportunities exist for greater regulatory convergence. The EMA-FDA ATMP cluster facilitates collaborative evaluation and information sharing. International guidelines from WHO and ICH provide frameworks for harmonizing technical requirements. Parallel scientific advice from regulatory and HTA bodies can help align evidence generation requirements across jurisdictions.

Conceptual Framework

Figure 1 (described below) presents an integrated framework for ATMP service management, illustrating the interconnections among three core domains:

Clinical Domain (inner circle): Patient identification and referral, leukapheresis, cell processing and manufacturing, cryopreservation and logistics, preconditioning, infusion, and post-treatment monitoring. This domain is supported by GMP infrastructure, quality management systems, and multidisciplinary staffing.

Business Domain (middle ring): Cost-based and value-based pricing mechanisms, managed entry agreements (financial and outcomes-based), annuity and amortization payment models, ATMP-specific funds, and public-private partnerships. This domain must balance manufacturer return on investment with health system affordability.

Regulatory Domain (outer ring): Compliance with national and regional regulatory frameworks (EMA, FDA, BPOM, etc.), GMP standards, pharmacovigilance requirements, hospital exemption provisions, and international harmonization initiatives. Cross-cutting elements include health technology assessment, real-world evidence generation, and ethical oversight.

The framework emphasizes that sustainable ATMP service delivery requires simultaneous optimization across all three domains, with continuous feedback loops between clinical evidence generation, business model adaptation, and regulatory evolution. Importantly, the framework also recognizes that successful ATMP implementation is not a linear process. Conflicting evidence across healthcare systems shows that clinical efficacy alone is insufficient; implementation success depends on the alignment of infrastructure, reimbursement, governance, workforce capacity, and ethical oversight.

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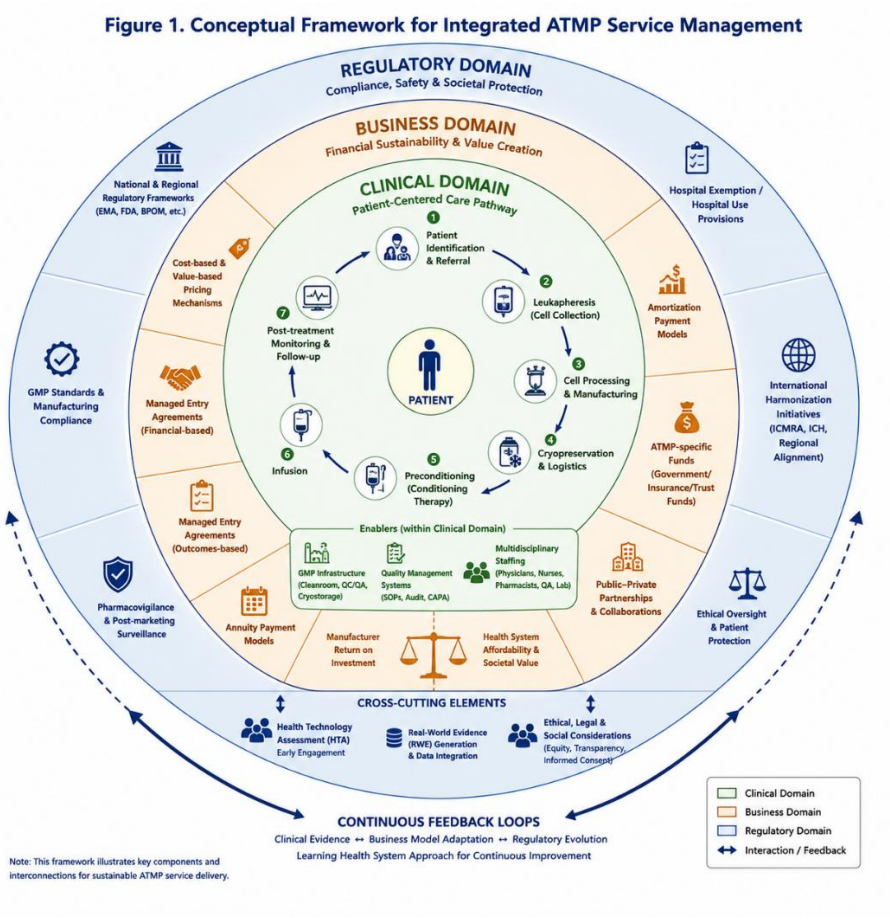

CONCLUSION

Effective ATMP service management requires integrated coordination across clinical operations, business strategy, and regulatory compliance. The reviewed evidence indicates that centralized hub-and-spoke models, particularly those built on established hematopoietic stem cell transplant infrastructure, can support efficient and equitable ATMP delivery. Early engagement with HTA bodies and payers is also essential, as regulatory approval alone does not ensure market access.

To improve implementation, policymakers should develop dedicated ATMP funding mechanisms, support transparent pricing and access dialogue, and invest in manufacturing and logistics infrastructure. Healthcare administrators should strengthen hub-and-spoke networks, quality management systems, workforce training, and partnerships with academic GMP facilities. Developers should generate robust clinical and real-world evidence while designing scalable and cost-efficient manufacturing processes. Regulators should continue international harmonization and ensure that adaptive pathways and hospital exemption frameworks prioritize safety, transparency, and patient access.

Overall, the transformative potential of ATMPs will depend not only on scientific innovation but also on sustainable management frameworks that address affordability, regulatory alignment, service capacity, and equity. Future empirical research should further evaluate optimal delivery models, cost-effectiveness, and long-term outcomes to guide policy and practice..

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest related to the preparation, authorship, or publication of this article. No financial, institutional, or personal relationships influenced the analysis, interpretation, or presentation of the findings in this narrative review.

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