

# Bridging the Regulatory Gap in Pakistan's Stem Cell Landscape

Nazia Abdul Rehman<sup>1</sup>, Ramla Shahid<sup>2</sup>

<sup>1,2</sup>Department of Allied Health Sciences, Islamabad Medical & Dental college, Islamabad, Pakistan

## Address of Correspondent

*nazia.rehman@imdcollge.edu.pk*

For millions of Leukemia, Thalassemia, chronic wounds, burn injury and other degenerative disorder patients in a country like Pakistan; stem cell treatment is not only a scientific pursuit, it is a profound beacon of hope. But as we sit on the cusp of revolution in regenerative medicine, our clinical progress is trudging along at a 'very slow pace' compared to its regional counterparts. Neighboring Countries including Iran reached eight times as much scientific output compared to us but our stem cell landscape is still described "in its infancy phase" rather developing or emerging stage.

In addition to Iran, the Republic of India has its National Guidelines on Stem Cell Research (NGSCR) in place since 2017,<sup>1</sup> making it a regional center which contains over forty research centers and hospitals with stem cell therapies and treatment activity. These regulations not only provide a more liberal approach to embryonic research but also place tight control measures. Stem cell byproducts and derivatives fall under the legal ambit of investigational new drugs of Drugs and Cosmetics Act 1940 of India.<sup>2</sup>

Throughout Islamic world, Stem cell research is diversified but is increasingly subject to regulations.<sup>3,4</sup> For example, Jordan took the lead in 2014 by establishing the Middle East's first statute, specifically addressing embryonic stem cells and related products.<sup>4</sup> Contrarily, Malaysia, which is one of the most predominantly Muslim nations, has progressive National Guidelines that have been recently updated in 2024 and which allow conducting research with adult stem cells but forbids the establishment of embryos to experiment with them.<sup>5</sup> On the other hand, Research using human embryos is banned by the official rule in Turkey, though Erciyes University actively promotes research on adult stem cells.<sup>3</sup> Further, other Gulf countries, such as the Saudi Arabia and Qatar, have modified their national laws in order to provide the legal basis of research using living organisms and cell based therapies.<sup>4</sup>

Regulatory scenario governing stem cell research among developed nations is clearer ranging from flexible to more restrictive system. China is now controlling the world in stem cell research and its regulations.<sup>6</sup> European countries, United States, and other developed countries embarked on developing their regulatory trails at the turn of the twenty-first century, devising specialized systems to regulate cell based technologies.<sup>7,8</sup> In contrast, Regulatory landscape in Pakistan stays stagnant and fragmented, with oversight dispersed across multiple authorities and without a unified, stem cell based therapies' specific framework. Such incoherence leaves researchers in uncertainty, reduces the potential of transnationalism, and creates issues with patient safety and ethical standard practices.

Although stem cell based products are technically regulated as biologicals by the Drug Regulatory Authority of Pakistan under the DRAP Act, 2012 and the Bio Study Rules, 2017.<sup>9,10</sup> However, Pakistan still doesn't have clear, comprehensive regulatory guidelines for stem cells, that separate research use, minimally manipulated autologous applications, advanced cell based medicinal products, and commercial therapeutic claims.<sup>11</sup> Current regulations mainly focus on registering biological products and approving clinical trials. They don't have detailed rules that are specific to new regenerative medicine practices.

National Bioethics Committee (NBC) separately guides the ethical oversight, while transplant related aspects may involve the Human Organ Transplant Authority, Although THOTA 2010 marked an important step in controlling illegal organ trafficking, many of its rules, made for the transplantation of non-regenerative solid organs like kidneys and hearts, no longer fit the scientific and clinical challenges of today's cell-based treatments.<sup>12,13</sup> Provincial bodies like Islamabad Healthcare Regulatory Authority (IHRA) and Sindh Healthcare Commission oversee healthcare service delivery. The abundance of the stakeholders who view their mandates in the most constricted manner creates conspicuous lack in

coordination, leading to a regulatory vacuum and inaccurate principles concerning translation of foundational research to standardized clinical therapies.

In the absence of harmonized and unified national guidelines that are specific to cell-based biotherapies, regulatory oversight will be assertive instead of proactive character; this position creates barriers to research compliance and at the same time creates new opportunities in the form of unregulated or commercially driven interventions.

An effective, strong regulatory regime based upon product regulation, ethical governance, clinical regulation and enforcement, or preferably built in a centralized, collaborative manner, would enhance patient protection and at the same time make responsible progress in the field of stem-cell research and therapeutics in Pakistan.

Regenerative medicine today, however, requires a far more specialized structure that differentiates between traditional tissue transplantation and Advanced Therapy Medicinal Products (ATMPs), such as living cell therapies, bioactive peptides and explants. There is a dire need to fill this void in Pakistan by the establishment of oversight model similar to National Pharmaceutical Regulatory Agency (NPRA), where DRAP can spearhead the authorization of clinical trials and post market surveillance.

Simultaneously, Provincial and Federal Regulatory authorities, like Islamabad Healthcare regulatory authority (IHRA) need to work in coordination with these institutions for developing and strictly implementing clinical guidelines to prevent patient safety violations within hospital premises. This transition from static, transplant centered model to dynamic framework which regulates cell-based products and treats them as biological drugs, Pakistan can ensure that specialized scientific innovations are no longer controlled by legal provisions which were never designed for the era of regenerative medicine.

DRAP may employ a specific model designed after Malaysian guidelines (Updated 2024), which make a clear distinction between various cell-based interventions and products, to establish a robust and forward-thinking regulatory framework in Pakistan. Malaysia uses a risk-based regulatory model that classifies medicinal products into the different classes. Class I Products are not highly processed items and are meant to be used in homologous applications, but Class II may be highly processed, or they

may be a new therapeutic modality. Applying a similar schema to the situation in Pakistan would enable regulatory authorities to regulate advanced therapies, especially biologics, by providing strict requirements of clinical trials, and leave conventional treatment within the scope of the established medical practice.

There is a strong need to conclude and draw a clear boundary between established clinical routines and innovative cell-based products. Meanwhile It is important to realize that cell based medicinal products and solid organ transplants are not the same as each of these is currently regulated under THOTA2010. Organ transplantation includes extraordinarily complex surgical procedures, stem -cell treatments provide regulating benefits that may be robbed using relatively less hazardous modalities. As they have quite different structural profiles and different risk spectra, it is wise to treat advanced cell therapies differently as ATMPs instead of dealing under organ-transplant therapies. This change of regulation would protect patient safety and maintain therapeutic efficacy while ensuring safe and effective treatment.

Another window which opened debate regarding cell-based therapies is unregulated use of peptides and exosomes in dermatology and wellness industry. To fill the "regulatory vacuum" authority should expand the regulatory blanket and add sections for non-cell-based biological products. For instance, Exosomes are novel biological products, or extracellular vesicles. They need a basic regulatory framework for preclinical safety and efficacy. Peptides and proteins, such as cytokines and growth factors from cell cultures, should be treated as biologically active substances under a risk-based model. By adopting the Malaysian model, which includes products from plant cells and chemically synthesized peptides, regulatory authority can ensure that "cell based" claims in the cosmetic and dermatology industries are scientifically verified.

By using the Malaysian and international models, DRAP can establish a multi-tier oversight system including:

1. Integrative Oversight: Coordinate with the National Bioethics Committee (NBC) for ethical review and HOTA for technical standards but maintain DRAP as the sole authority for clinical trial authorization and market surveillance of cell-based products.
2. Defining Cell types and sources: A more comprehensive approach should be adopted for

defining all cell types categorizing under relevant sources for articulated regulatory framework.

3. Risk Based Sections: Create specific regulatory pathways for:
  - Live Cell Therapies: Requiring full GMP licensing and Phase I-III trials.
  - Cell Secretory Products (Exosomes/Peptides): Regulated as biologics focusing on purity and potency.
  - Plant Based Products: Subject to standardized "Natural Product" or biologic drug evaluation.

It is a systematic way of encouraging scientific innovation without being limited to generalized regulations of organ transplantation.

In order to make Pakistan a regional center of regenerative medicine, there is a need to focus on institutional structure and educational change in a dual manner. We must now set up Independent Centers of Excellence in the major metropolitan centers -Karachi, Lahore, and Islamabad, which include research laboratories and complementary clinical hospitals. Also, medical schools should include extensive stem-cell courses in the curriculums, in this way, equipping our future workforce with the type of knowledge and skills they will need to deal with ethical and technical issues presented by this fast-moving field.

The innovative mindful character of GAK Healthcare International has prompted an indeed important discourse to drag Pakistan out of its existing regulatory deficit. We pledge to design policies which protect patients and still promote responsible development of stem-cell research therefore cultivating pure scientific development. Through collaboration with the Islamabad Healthcare Regulatory Authority (IHRA) and the Drug Regulatory Authority of Pakistan (DRAP), we hope to establish an effective, ethically sound, framework that will ensure the safety and scientific soundness of stem-cell therapies, in effect, providing the researchers with the necessary resources to engage in responsible therapeutic innovation.

We are trying to substitute the current disjointed system with a rights-based paradigm. GAK Healthcare International has already secured its standing by developing the fully controlled Stem Cell Excellence Centre in capital hence showing its interest in safety, ethical integrity and high quality clinical and research practices. Pakistan has the ability to flourish in regenerative medicine sector; it needs to bring in place the

robust regulatory policies to worldwide standards without compromising our cultural and religious traditions.

Hope alone is not an outcome; it is the catalyst for the legislation our patients deserve.

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