



Republic of the Philippines
Professional Regulation Commission
Manila



SECOND POSITION PAPER OF THE PROFESSIONAL REGULATORY BOARD OF MEDICINE ON STEM CELL THERAPY AND RELATED CONCERNS

The Professional Regulation Commission and the Professional Regulatory Board of Medicine constitute the regulatory body for the practice of medicine in the country, As part of their regulatory functions with quasi-judicial and quasi-legislative powers, they hereby issue the following statements on matters dealing with the competencies of specialists, the practice of stem cell therapy, the principle of innovative therapy, and the SEC registration of PSSCM.

At the outset, the following delineation of authority should be made clear:

- a. The government regulatory body for the practice of medicine: Professional Regulation Commission (PRC) and the Professional Regulatory Board of Medicine (PRBOM). The PRC/PRBOM license physicians and regulate the practice of the profession.
- b. The government regulatory body for hospitals, clinics and laboratories: Department of Health (DOH). The DOH licenses hospitals, clinics and laboratories.
- c. The government regulatory body for drugs and stem cell solutions/products: Food and Drug Administration (FDA). The FDA licenses the use of drugs, stem cell products and solutions.

Main consideration: Patient Safety

The International Association of Medical Regulatory Authorities (IAMRA) lists the Board of Medicine as the regulatory authority in the Philippines. The ASEAN MRA for Medical Practitioners included the Professional Regulation Commission and the Professional Regulatory Board of Medicine as the Professional Regulatory Authorities (PRA) for the Philippines

The PRBOM agrees with the IAMRA declaration that the mandate of medical regulatory authorities is to **protect, promote and maintain the health and safety of the public by ensuring proper standards for the profession of medicine.**

For the protection of the public, the PRBOM hereby defines the Quality Standards for specialists most qualified and most competent to practice and to conduct research in stem cell therapy.

I. QUALITY STANDARDS FOR SPECIALISTS TO PRACTICE STEM CELL THERAPY FOR PROVEN INDICATIONS (Based on US FDA)

For proven indications, the PRBOM mandates that based on the disorders/diseases, the appropriate specialists, based on education, training, clinical experience and certification, to perform treatment are the following:

1. Bone marrow transplantation for hematologic disorders/diseases: Diplomates and Fellows of the Philippine Society of Hematology and Blood Transfusion, Philippine Society of Pediatric Hematology (PSPH).
2. Corneal resurfacing with limbal stem cells for ocular disorders/diseases: Diplomates and Fellows of the Philippine Academy of Ophthalmology.

II. QUALITY STANDARDS FOR SPECIALISTS TO CONDUCT CLINICAL TRIALS IN STEM CELL THERAPY FOR UNPROVEN INDICATIONS (Based on US FDA)

For unproven indications, the PRBOM mandates that based on the disorders/diseases, the appropriate specialists (based on education, training, clinical experience and certification) to conduct clinical trials are the following:

