Introduction

Stem cells are undifferentiated cells with the capacity to evolve into diverse cell types and tissues. Within the human body, they function as an internal repair mechanism during both early development and throughout life.[1] Stem cells possess distinctive differentiation capabilities, offering much potential for medical treatments through stem-cell-based therapies. These therapies can restore damaged or lost cells, potentially transforming medical treatments and regenerative medicine.

However, the ethical complexities surrounding the boundary-crossing nature of stem cell usage present regulatory challenges distinct from those of traditional medicine.[2] One illustration of this is the emergence of private laboratories due to the increasing industry interest in stem cell transplantation. These facilities offer services for the collection, processing, and utilisation of human adult stem cells for therapy, sourced from various biological materials, and operate under existing regulations and guidelines, overseen by registered medical practitioners.[3]

Recognising the need for a proper mechanism to oversee the field, Malaysia has started formulating regulations to govern stem cell research and therapy based on sound scientific principles and international best practices, modelled after benchmarked regulatory authorities to balance scientific advancement with ethical principles and public safety.[4]

Regulatory Framework

Currently, there are no enforced laws regulating stem cell research and therapies, except that such practices must comply with the Private Healthcare Facilities and Services Act 1998.[5] The only regulation available is provided under the Guidelines For Stem Cell Research and Therapy, a document issued by the Ministry of Health ("**MOH**") in 2009 ("**MOH Guidelines"**),

as well as the Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products ("**CGTPs**") in Malaysia issued by the National Pharmaceutical Regulatory Agency (formerly the National Pharmaceutical Control Bureau) in 2016 ("**NPRA Guidelines**").

The MOH Guidelines

The MOH Guidelines were developed in recognition of the crucial need for local scientists to stay abreast of current advances in science and to encourage their involvement in stem cell research within an ethical environment. Under MOH's patronage, the Medical Research and Ethics Committee ("**MREC**") and the National Stem Cell Research and Ethics sub-committee ("**NSCERT**") were established. The former appears to have more authority, particularly in granting licences and/or approval for research, whereas the latter is tasked with reviewing research applications.[6]

Additionally, the guideline lays down permissible and prohibited stem cell research and therapies, calls for autonomous and informed decisions in the production of human embryos for infertility treatment, prohibits the use of cash or in-kind payments for the donation of embryos for research and emphasises the donor's right to withdraw consent until the blastocysts are used for cell line derivation.[7]

In ensuring research is conducted within ethical boundaries, the MOH Guidelines state that all research activities involving stem cells derived from humans or animals must undergo review by the relevant bodies before they can proceed. There is a slight difference between seeking approval for research for academic purposes and approval for clinical trials. Before receiving clearance from NSCERT, academic institutions – both private and public – must obtain institutional-level approval from bodies like the Institutional Ethics Committee ("**IEC**") or the Institutional Review Board ("**IRB**").[8]

On the other hand, non-academic research conducted in both public and private research laboratories requires direct NSCERT permission.[9] Before receiving NSCERT permission, clinical trials and research involving human subjects in both public and private facilities must register with the National Medical Research Registry ("**NMRR**").[10] The NMRR provides information to the public by acting as a platform for verification.

Additionally, centres conducting Human Stem Cell Therapy (HSCT) are required to seek accreditation from NSCERT. Adherence to the MOH Guidelines is mandatory, especially since both the person in charge and specialists involved in transplant procedures – being registered medical practitioners – bear accountability for all aspects of the procedures and their outcomes.[11]

The NPRA Guidelines

On the other hand, the NPRA Guidelines mostly provide information for manufacturers, applicants, healthcare professionals as well as the general public for the registration of

CGTPs in Malaysia. CTGPs are classified as medicinal products under the Control of Drugs and Cosmetic Regulations 1984 as they possess properties intended for medicinal purposes, [12] i.e. treating or preventing diseases and restoring physiological functions through pharmacological, immunological, or metabolic actions.[13] The NPRA Guidelines are relevant to all products using stem cells as starting material. It also lays down specific rules on registration and its data requirements (i.e. Chemistry, Manufacturing Control (CMC), nonclinical and clinical data), supervision, risk management plan (RMP) and pharmacovigilance of CGTPs.[14]

Ethical Concerns and Considerations

The MOH Guidelines also address ethical concerns, particularly regarding the source of stem cells used for research. Generally, research on adult stem cells is more contentious than on embryonic stem cells. The fact that embryonic stem cells are derived from embryos raises questions on the destruction of human embryos, which some consider to be morally equivalent to taking a human life. This debate hinges on differing beliefs as to when human life begins. A national fatwa on stem cell research issued by the Malaysia National Fatwa Council was fully adopted and reflected in the MOH Guidelines.[15] The guidelines state that research on stem cells derived from foetal tissues from legally performed terminations of pregnancy and the use of embryonic stem cell lines are allowed, as well as research on embryonic stem cells derived from surplus embryos.

However, it prohibits the creation of human embryos for research purposes, whether through methods like assisted reproductive technology or somatic cell nuclear transfer. Additionally, any research involving the growth of human embryos in a lab dish for more than fourteen (14) days or until the formation of the primitive streak begins is also prohibited.

In contrast, most stem cell therapies, whether embryonic or adult, are still experimental and in the research stage. As a result, registered medical practitioners must strictly adhere to the MOH's existing guidelines, which include the rules on Cord Blood Banking and Haematopoietic Stem Cell Therapy. The MOH Guidelines also delineate different indications of "potential/development/experimental" for different types of stem cell therapies. Therapy using human embryonic stem cells is considered experimental and must first be approved by the IRB or IEC.

Conclusion

In conclusion, the regulatory landscape surrounding stem cell research and therapy in Malaysia reflects a delicate balance between scientific advancement and ethical considerations. Moving forward, ongoing communication and collaboration among regulatory authorities, healthcare practitioners, and researchers will be crucial in navigating Malaysia's evolving landscape of stem cell research and therapy, ensuring that scientific advancement is made ethically and responsibly.

---

1. Dr. Yvonne Khoo Siew Khoo and Dr. Azizah bt. Ab Ghani, "Stem Cells" (MyHealth Ministry of Health Malaysia, 24 June 2015) <http://myhealth.moh.gov.my/en/stem-cells2/#:~:text=Stem%20cells%20are%20undifferentiated%20cells,early%20growth%20and%20throughout%20life.>.
2. National Pharmaceutical Control Bureau, "Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) In Malaysia" (Ministry of Health Malaysia, 2015) <https://www.npra.gov.my/index.php/en/guideline-bio/1527314-guidancedocument-and-guidelines-for-registration-of-cell-and-genetherapy-products-cgtps-in-malaysia-2.html>.
3. Medical Development Division, "Guidelines for Stem Cell Research and Therapy" (Ministry of Health Malaysia, 2009) <https://www.moh.gov.my/index.php/database_stores/attach_download/681/118>.
4. National Pharmaceutical Control Bureau, "Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) In Malaysia" (n 2).
5. Academy of Sciences Malaysia, "Advisory Report on Stem Cells Ageing and Regenerative Medicine" (Academy of Sciences Malaysia, 2013) <https://www.akademisains.gov.my/asmpub/?mdocs-file=156>.
6. Mohammad Firdaus Bin Abdul Aziz, Michael Morrison and Jane Kaye, "Regulating human stem cell research and therapy in low and middle-income countries: Malaysian perspectives" (2018) 37(1) New Genetics and Society 2.
7. ibid.
8. Datuk Dr. Noor Hisham bin Abdullah, "Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bilangan 4/2015: Tatacara Prosedur Permohonan Berkaitan Penyelidikan Sel Stem dan Cell - Based Therapies" (2015) Director General of Health Malaysia <https://www.moh.gov.my/moh/resources/Penerbitan/Perkhidmatan%20OnG%20&%20Ped/STEM%20CELL/Tatacara_Prosedur_Permohonan_Berkaitan_Penyelidikan_Sel_Stem_Dan_Cell_Based_Therapies.zip>.
9. ibid.
10. Nishakanthi Gopalan, Siti Nurani Mohamed Noor and Mohd Salim Mohamed, "The Pro-Medical Tourism Stance of Malaysia and How it Affects Stem Cell Tourism Industry" (2021) 11(2) Sage Open <https://journals.sagepub.com/doi/epub/10.1177/21582440211016837>.
11. ibid.
12. Control of Drugs and Cosmetic Regulations 1984.
13. National Pharmaceutical Control Bureau, "Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) In Malaysia" (n 2).
14. ibid.
15. Medical Development Division, "Guidelines for Stem Cell Research and Therapy" (n 3) 47 - 51.

Written by:

Ling Shin Ying
Associate
lingshinying@azmilaw.com

Nurfarahin Zainal Abidin
Trainee Solicitor
farahinzainalabidin@azmilaw.com

Corporate Communications
Azmi & Associates
17 July 2024