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**CIRCULAR NO: 74/2020**

**Date** : 03<sup>rd</sup> November 2020  
**File Ref No.** : ***PSS – 7-1: Medicinal Product Safety Alert #. 2/2020***  
**To.** : All Health care Professionals  
: All Local Importers, Distributors & Retailers of Stem Cell & Related Products  
: General Public, Patients & Consumers  
  
**Re** : **Public Safety Alert on Marketing & Medical Use of Unapproved Stem Cell (STC 30 - SuperLife) Products in PNG**

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This Circular is to warn and inform the public, especially patients, health care practitioners (including conventional & alternate/traditional medicine practitioners), importers, retailers, Patient support groups and clinics as a Public Safety Warning pertaining to the illegal marketing and use of unapproved Stem Cell products in PNG.

The National Department of Health (NDoH) has observed that there is a proliferation of a large number of unregistered distributors of unapproved Stem Cell products in PNG. The Health Department hereby strongly warns on the illegal marketing and widespread use of Unapproved **Stem Cell (STC30- SuperLife)** and other related (exosome) Products derived from cells as “**miracle drugs**” to treat or self-treat multiple diseases and variety of medical conditions. The fast proliferation of clinics and individual health care professionals prescribing and offering the Stem Cell treatment in PNG poses a significant long-term risk to public health and could cause multiple instances of patient harm, including blindness and life-threatening infections.

There is a safety concern based on expert reports from US FDA and TGA Australia warning that some of these “Stem Cell therapies” are likely to cause significant harm. Expert reports have revealed that individuals treated with Stem Cells have developed complete eye blindness and tumours (further cancerous cell growth).

It is noted that many unregistered distributors in PNG are selling these Stem Cell Products that have not been approved by national or international drug regulatory authorities. The following Stem Cell products are currently distributed in PNG:

- \* STC 30(Superlife Total Care)
- \* SCC15(Superlife Colon Care)
- \* SIC(Superlife Immune Care)
- \* SNC(Superlife Neuron Care)

These complementary products are currently seen as experimental products because they have not undergone their stringent clinical testing to fully confirm their risk-benefit claims and therefore, have not been officially approved by any stringent international drug regulatory authorities to treat multiple diseases and other life-long debilitating medical conditions.

**Be aware and cautious that there is no “magic drug” that cures all diseases.** Such claims are not scientifically proven and the products are of high risk to patients and consumers apart from the claimed benefits. Other potential safety concerns for unproven Stem Cell treatments include:

- The ability of cells to move & change into inappropriate cell types or multiply,
- Failure of cells to work as expected, and
- The growth of tumors/Cancerous cell growth in the body.

Stem cells are a type of special products that are strictly regulated and cannot be advertised to the public without prior approval from regulators. Therefore, the advertising of Stem Cell products is subject to compliance with special advertising requirements in order to protect consumers. Please be warned that any unauthorised advertising in any form of the Stem Cell products of any therapeutic claims is in breach of the **Medicines & Cosmetics Act 1999**. All medicinal products advertising must be assessed, validated and approved by the National Department of Health to protect the public health.

The NDoH remains committed to protecting patients. Our work to ensure compliance with the law and regulations of medicinal products does not take away from our firm commitment to advance an efficient path for the safe and effective development, distribution and use of novel regenerative medicine and alternative or complementary therapies and to help foster beneficial new innovations.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the **Pharmacovigilance & Drug Information Officer, Mr. Ronald Jorim at PNG Drug Information & Pharmacovigilance Unit** at the Pharmaceutical Services Standards Branch of the National Department of Health through Email: [pngdipu@gmail.com](mailto:pngdipu@gmail.com) or on telephone (+675) 301 3886.

Refer to attachment regarding Stem Cell treatment.

Thank you for your vigilance and adherence in protecting public health.



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**Dr. Osborne Liko**  
Secretary for Health



**STEM CELL PRODUCTS**

- Be cautious and know the long-term Benefits & Risks of what you are taking to treat your disease.
- Be warned and informed that there is "No Magic Drug" that Cures all Diseases.
- Are they scientifically proven and regulated by stringent drug regulatory authorities in other countries and regulated, approved and registered in the country of Manufacture?

Super Life Product in PNG

Powerful product **STC30**

**SuperLife Total Care 30**  
STC30 CAN ALLEVIATE MORE THAN 130 DISEASES

**Diseases Treated by STC 30**

ANTI-AGING	ARTHRITIS	CATARACTS	CANCER	HEART PROBLEMS
JOINT PAINS	VIGOUR	STROKE	BURNS	LIVER PROBLEMS
GOUT	KIDNEY DISEASE	DIABETES	SKIN DISEASE	Blood Pressure

**TESTIMONIES PROVEN FROM STC 30**

Before After

1. I have been suffering from...  
2. I have been suffering from...  
3. I have been suffering from...

**STEM CELL WORKS IN 6 WAYS**

- Rejuvenates aged cells
- Replicates good cells
- Restores sick cells
- Replaces dead cells
- Repairs damaged cells
- Cleanses the blood & brings the body to normal functionality

Florence Magua and 24 others

**SuperLife**

**WHAT ARE STEM CELLS**

- ✓ **STEM CELLS** are cells that have regenerative properties and are able to Multiply at Exceedingly Rapid Rates
- ✓ **STEM CELLS** are the Natural Renewal System of the body providing an Effective means for Cell and Tissue Renewal & Repair
- ✓ Each time a **STEM CELL** is created, either it will become another **STEM CELL** & continue budding off creating more of its own, or it will become a Specialized Cell & go on to become any part of your Body; **KIDNEYS, SKIN, EYES** etc.
- ✓ **STEM CELLS** are capable of correcting Physical Deficiencies
- ✓ **STEM CELLS** are SMART! They know how to find injured Cells in the body and initiate a healing process by themselves.

**WHY STEM CELL THERAPY?**

- ✓ **STEM CELL THERAPY** is the use of **STEM CELL** to treat or prevent a disease!
- ✓ **STEM CELL THERAPY** allows for the Repairing and Rejuvenation of the Body from damaged Cells caused by various illnesses.
- ✓ **STEM CELL THERAPY HELPS TO:**
  - ✓ RESTORE DEAD CELLS
  - ✓ REJUVENATE AGED CELLS
  - ✓ REPLACE SICK CELLS
  - ✓ REPLICATE GOOD CELLS
  - ✓ REPAIR DAMAGED CELLS
- ✓ It is now Proven that basic **STEM CELL NUTRITIONAL THERAPY** can enhance our **STEM CELLS** in a Significant Way.
- ✓ **STEM CELL THERAPY** can for an example, Regrow New and Healthy Cartilage in Knee Joints

*"REGENERATIVE" MEDICINE IS THE HEALTH CARE SOLUTION OF THE FUTURE.*  
© 2015 SUPER LIFE. ALL RIGHTS RESERVED. YOUR BODY IS YOUR MOST VALUABLE ASSET. TAKE CARE OF IT NOW TO ENJOY THE REALITY OF A LONG, HEALTHY LIFE.

**Tissue Renewal**  
Tissues & Organs Constantly Turnover

90 days	5 days	4 years
4 years	15 - 20 years	2- 3 years
		20 - 30 years

SuperLife





## **STEM CELL PRODUCTS**

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- **Be warned and informed that there is “No Magic Drug” that Cures all Diseases.**
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## **US Food and Drug Administration Alert on Stem Cell**

### **Public Safety Alert Due to Marketing of Unapproved Stem Cell and Exosome Products**

**AUDIENCE:** Health Professional, Patient, Consumer, Risk Manager

**ISSUE:** FDA is informing the public, especially patients, health care practitioners, and clinics, of multiple recent reports of serious adverse events experienced by patients in Nebraska who were treated with unapproved products marketed as containing exosomes. FDA is carefully assessing this situation along with our federal and state partners. Certain clinics across the country, including some that manufacture or market illegal “stem cell” products, are now also offering exosome products to patients. They deceive patients with unsubstantiated claims about the potential for these products to prevent, treat or cure various diseases or conditions.

**BACKGROUND:** As a general matter, exosomes used to treat diseases and conditions in humans are regulated as drugs and biological products under the Public Health Service Act and the Federal Food Drug and Cosmetic Act and are subject to premarket review and approval requirements. Clinics may claim that they these products do not fall under the regulatory provisions for drugs and biological products – that is simply untrue. There are currently no FDA-approved exosome products.

The clinics currently offering these products outside of FDA’s review process are taking advantage of patients and ultimately puts patients at risk by either delaying treatment with legitimate and scientifically sound treatment options, or worse, posing harm to patients, as evidenced by these recent reports of adverse events.

**RECOMMENDATION:** Patients considering treatment with exosome products in the United States should:

- Ask if the FDA has reviewed the treatment.
- Ask the clinical investigator to give you the FDA-issued Investigational New Drug Application (IND) number and the chance to review the FDA communication acknowledging the IND. Ask for this information before getting treatment and follow up with your personal health care provider to confirm this information.
- Sign a consent form. Because there are no approved products, patients must sign a consent form to participate in a clinical trial that requires an IND application. The consent form also identifies the Institutional Review Board (IRB) that assures the protection of the rights and welfare of human subjects. Make sure you understand the entire process and known risks before you sign. You also can ask the study sponsor for the clinical investigator’s brochure, which includes a short description of the product and information about its safety and effectiveness.

If you are considering treatment using an exosome product in another country you should:

- Learn about regulations that cover products in that country.
- Know that FDA does not have oversight of treatments done in other countries. FDA typically has little information about foreign establishments or their products.
- Be cautious. If you’re considering an exosome product in a country that may not require regulatory review of clinical studies, it may be hard to know if the experimental treatment is reasonably safe.