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HSA Health Sciences Authority

CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) ADVERSE REACTION REPORT

Vigilance and Compliance Branch • Health Products Regulation Group • Health Sciences Authority

HSA AE Adverse Events Watch

*Please indicate the type of report: ☐ Initial Report ☐ Follow-up report

I PARTICULARS OF PATIENT

*Name/Initials: ..... Weight: ..... kg

*NRIC/FIN/Passport no: ..... Date of birth/Age: ..... Sex: ☐ Male ☐ Female

Ethnic group: ☐ Chinese ☐ Indian ☐ Malay ☐ Others (Please specify): .....

II DETAILS OF THE ADVERSE REACTION

*Date of onset (dd/mm/yy): .....

*Outcome: ☐ Recovered (Date): ..... ☐ Not yet recovered

☐ Fatal (Date of Death): ..... ☐ Unknown

Sequelae (any permanent complications of injuries as a result of the adverse reaction): ☐ Yes ☐ No ☐ Unknown

*Description of Adverse Reaction:

.....

.....

.....

III SUSPECTED CTGTP

*Brand name / Product Description: (e.g. bone marrow mesenchymal stem cells, chondrocytes)	
Indication for treatment:	Batch / Lot no:
Dosage: (e.g. 50 million cells per dose)	Route of Administration:
Frequency: (e.g. one injection per week)	Dose no. (e.g. 1st, 2nd):
Donor type: ☐ Autologous ☐ Allogeneic	
Origin of cells/tissues (tick all that apply): ☐ Embryonic ☐ Cord ☐ Foetal ☐ Adult ☐ Induced Pluripotent	
Name of place of administration:	Start date (dd/mm/yy):
	Stop date (dd/mm/yy):

Other concomitant medications (including complementary medicines, consumed at the same time and/or 3 months before):

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Other relevant information e.g. pre-existing medical conditions, pregnancy, allergies, laboratory results:

.....

.....

IV MANAGEMENT OF ADVERSE REACTION

1. Do you consider the reaction to be serious? ☐ Yes ☐ No

2. If yes, please indicate why the reaction is considered to be serious (please specify):

- ☐ Results in death
- ☐ Is life-threatening
- ☐ Requires inpatient hospitalisation or prolongation of existing hospitalisation
- ☐ Results in persistent or significant disability/incapacity
- ☐ Is a congenital anomaly/birth defect
- ☐ Other medically important conditions, please specify: .....

3. Hospitalisation (following adverse reaction): ☐ Yes ☐ No ☐ Already hospitalised

4. Was treatment given? ☐ No ☐ Yes, please specify: .....

5. Relatedness of product to adverse reaction ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unknown

V PARTICULARS OF REPORTING PERSON

*Name: ..... *Profession: .....

Contact no: .....

*Email address: .....

Date of report: .....

*Name and address of place of practice	Signature

An asterisk (*) indicates mandatory fields

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EXPLANATORY NOTES

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Any information related to the identities of the reporter and patient will be kept confidential.

WHAT TO REPORT

An adverse reaction to a CTGTP product means any adverse effect that is unintended and occurs in association with the use or administration of the product at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction or modification of physiological function.

A serious adverse reaction to a CTGTP product means an adverse reaction that

a) results in a person's death;
b) threatens a person's life;
c) results in a person being hospitalised as an inpatient or prolongs a person's existing stay in hospital;
d) results in a person's persistent or significant disability or incapacity;
e) results in a congenital anomaly or birth defect; or
f) is judged to be medically important even though the event might not be immediately life-threatening or result in death or hospitalisation, but might jeopardise the person or might require intervention to prevent one of the other outcomes listed above.

HSA encourages the reporting of all suspected adverse reactions associated with CTGTPs.

Please do not be deterred from reporting because some details are not known. Additional pages may be attached if required.

SUBMISSION OF FOLLOW-UP REPORTS

Please indicate that it is a follow-up report. It is very important that follow-up reports are identified and linked to the original report.

HOW TO REPORT

Mail	Phone	Email	E - reporting
Vigilance and Compliance Branch **Health Products Regulation Group** **Health Sciences Authority** 11 Biopolis Way #11-03 Helios Singapore 138667	(65) 6866 1111	HSA_productsafety@hsa.gov.sg	http://www.hsa.gov.sg/adverse-events