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No. S 801

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (CELL, TISSUE AND GENE THERAPY PRODUCTS) (AMENDMENT NO. 2) REGULATIONS 2023

In exercise of the powers conferred by sections 45 and 72(1) of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Cell, Tissue and Gene Therapy Products) (Amendment No. 2) Regulations 2023 and come into operation on 18 December 2023.

Amendment of regulation 2

2. In the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021) (called in these Regulations the principal Regulations), in regulation 2(1) —

(a) delete the definitions of “nursing home” and “nursing home licensee”;

(b) replace the definition of “personnel” with —

““personnel”, in relation to a healthcare service licensee providing a licensable healthcare service, means any individual employed or engaged by the healthcare service licensee to assist the healthcare service licensee in providing the licensable healthcare service;”;
and

(c) in the definition of “traceability”, in paragraph (d)(i), delete “a nursing home,”.

Amendment of regulation 9

3. In the principal Regulations, in regulation 9(a) —
- (a) in sub-paragraphs (i) and (ii)(A), delete “nursing home licensee or” wherever it appears; and
 - (b) in sub-paragraphs (i) and (ii)(A), delete “, as the case may be” wherever it appears.

Amendment of regulation 12

4. In the principal Regulations, in regulation 12 —
- (a) in the regulation heading, delete “**nursing home licensees and**”;
 - (b) in paragraph (1), delete sub-paragraph (a);
 - (c) in paragraph (1)(b), delete sub-paragraph (i); and
 - (d) in paragraph (2)(b), delete “nursing home,”.

Amendment of regulation 15

5. In the principal Regulations, in regulation 15(1) —
- (a) in sub-paragraphs (b)(ii), (c)(i) and (ii), (d) and (ea)(i) and (ii), delete “nursing home licensee or” wherever it appears;
 - (b) in sub-paragraph (c)(ii), delete “(as the case may be)”;
 - (c) in sub-paragraphs (c)(ii), (d) and (ea)(ii), delete “, as the case may be”;
 - (d) in sub-paragraph (e), delete sub-paragraph (i);
 - (e) in sub-paragraph (e)(ii), delete sub-paragraph (A);
 - (f) delete sub-paragraph (eb); and
 - (g) in sub-paragraph (ec), delete sub-paragraph (i).

Amendment of regulation 16

6. In the principal Regulations, in regulation 16(1), delete “(eb),”.

Amendment of regulation 18

7. In the principal Regulations, in regulation 18 —
- (a) in paragraph (1), delete sub-paragraphs (a) and (c);
 - (b) in paragraphs (2), (3)(a) and (b) and (4), delete “nursing home licensee mentioned in paragraph (1)(a) or (c) or”;
 - (c) in paragraphs (2) and (3)(a), delete “, as the case may be”;
 - (d) in paragraph (3)(b), delete “(as the case may be)”;
 - (e) in paragraph (4), delete “as the case may be,”.

Amendment of regulation 21

8. In the principal Regulations, in regulation 21, delete paragraph (b).

Amendment of regulation 26

9. In the principal Regulations, in regulation 26(1)(b)(i), delete “nursing home or” wherever it appears.

Amendment of regulation 33

10. In the principal Regulations, in regulation 33(1)(b), delete “, (eb)”.

Amendment of regulation 34

11. In the principal Regulations, in regulation 34 —
- (a) in paragraph (2)(h), replace “nursing home, licensed retail pharmacy,” with “licensed retail pharmacy or”; and
 - (b) in paragraph (3), delete “nursing home or”.

Amendment of regulation 40

12. In the principal Regulations, in regulation 40(a)(iii) —
- (a) delete “nursing home licensee or” wherever it appears; and
 - (b) delete “(as the case may be)”.

Amendment of regulation 53

13. In the principal Regulations, in regulation 53(1)(b), replace “an active substance or” with “a”.

Amendment of regulation 54

14. In the principal Regulations, in regulation 54(1)(b), replace “an active substance or” with “a”.

[G.N. Nos. S 1076/2021; S 451/2022; S 437/2023]

Made on 24 November 2023.

BENJAMIN ONG
*Chairperson,
Health Sciences Authority,
Singapore.*

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(To be presented to Parliament under section 72(5) of the Health Products Act 2007).