
First published in the *Government Gazette*, Electronic Edition, on 22nd September 2011 at 5:00 pm.

No. S 542

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(COMPOSITION OF OFFENCES)
REGULATIONS 2011

ARRANGEMENT OF REGULATIONS

Regulation

1. Citation and commencement
 2. Compoundable offences
 3. Amendment of Health Products (Medical Devices) Regulations 2010
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In exercise of the powers conferred by section 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Composition of Offences) Regulations 2011 and shall come into operation on 3rd October 2011.

Compoundable offences

2. The following offences may be compounded in accordance with section 65 of the Act by the Chief Executive or any officer of the Authority authorised in writing in that behalf by the Chief Executive:

- (a) an offence under section 12(6)(a), 13(6)(a), 14(4), 15(2), 16(2)(a), 17(3), 18(2), 19(2), 20(3), 21(3), 23(3)(a), 35(4), 36(5), 40(3), 41(2), 42(5)(a), 43(3), 44(3)(a), 49(5)(e), (9) or (11), 50 or 66(4) of the Act;

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- (b) an offence under regulation 4(3), 10(3) or 11(4)(a) of the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007 (G.N. No. S 683/2007);
- (c) an offence under regulation 13A(3), 31(5), 32(2), 36A(5), 37, 38(3), 39(3), 39A(3), 39B(3), 40(2), 41(3), 43(2), 44(4), 45(3), 46(4), 47(3), 48(6) or (7)(b) or 49(5) or (6)(b) of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010);
[S 540/2016 wef 01/11/2016]
- (d) an offence under regulation 21(4), 31(3), 32(4), 33(3), 40, 41(6) or (7)(b), 42(4) or (5)(b), 43(2), 44(3), 45(2), 46(8), 48(7) or 65(3) of the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016);
[S 540/2016 wef 01/11/2016]
- (e) an offence under regulation 7(5) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);
[S 540/2016 wef 01/11/2016]
- (f) an offence under regulation 15(2) of the Health Products (Advertisement of Therapeutic Products) Regulations 2016 (G.N. No. S 333/2016), renamed as the Health Products (Advertisement of Specified Health Products) Regulations 2016 from 1 March 2021;
[S 540/2016 wef 01/11/2016]
[S 150/2021 wef 08/03/2021]
- (g) an offence under regulation 29(1)(a) of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016) but only in respect of a contravention of regulation 4(4) or (6), 5(1), (2), (3), (4) or (6), 6, 7(2), 8(1), 9(1), 10(1), (2), (4) or (6), 11(1), (2) or (3), 12(1), (2), (3) or (4), 13(1) or (2), 14, 15, 16(1) or (9), 17(3), (4) or (5), 18(1), 19(3), 22(2), 23(1) or (3), 23A(1), (3) or (4), 24(1), (2) or (4), 25(1), (2), (3) or (4) or 26(1), (2), (3) or (4) of those Regulations;
[S 540/2016 wef 01/11/2016]
[S 150/2021 wef 08/03/2021]

- (h) an offence under regulation 24(1)(a) of the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016), renamed as the Health Products (Clinical Research Materials) Regulations 2016 from 1 March 2021;
[S 540/2016 wef 01/11/2016]
[S 150/2021 wef 08/03/2021]
- (i) an offence under regulation 17(3), 19(5), 23, 24(5) or (6)(a), 25(3), 26(3) or 27(2) of the Health Products (Oral Dental Gums) Regulations 2016 (G.N. No. S 539/2016);
[S 540/2016 wef 01/11/2016]
[S 150/2021 wef 08/03/2021]
- (j) an offence under regulation 28(4), 32(3), 33(4), 34(5), 35(3), 44, 45(6) or (7)(b), 46(2), 48(4) or (5)(b), 49(2), 50(3), 51(2) or 56(3) of the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021).
[S 150/2021 wef 08/03/2021]

Amendment of Health Products (Medical Devices) Regulations 2010

3. Regulation 51 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) is deleted.

Made this 16th day of September 2011.

EDISON LIU
Chairman,
Health Sciences Authority,
Singapore

[HAS (HRPG) 401:04/01-000; AG/LLRD/SL/122D/2010/4 Vol. 1]

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