L.N. 319 of 2020

MEDICINES ACT
(CAP. 458)

Active Implantable Medical Devices (Amendment) Regulations, 2020

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister for Health, after consultation with the Licensing Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Active Implantable Medical Devices (Amendment) Regulations, 2020 and these regulations shall be read and construed as one with the Active Implantable Medical Devices Regulations hereinafter referred to as the "principal regulations".

S.L. 427.10.

Amends regulation 2 of the principal regulations.

2. Sub-regulation (2) of regulation 2 of the principal regulations shall be amended as follows:

(a) in paragraph (a) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority"; and

(b) in paragraph (b) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority".

Amends regulation 3 of the principal regulations.

3. Regulation 3 of the principal regulations shall be amended as follows:

(a) the definitions "Market Surveillance Directorate", "Regulatory Affairs Directorate" and the marginal notes "S.L. 419.03" thereof wherever they occur shall be deleted; and

(b) immediately after the definition "medical device" there shall be added the following new definition:

" "Medicines Authority" means the Authority as established under article 4 of the Medicines Act;".

Cap.458.

Amends regulation 6 of the principal regulations.

4. Regulation 6 of the principal regulations shall be amended as follows:

(a) in sub-regulation (9) thereof, the words "Director of Regulatory Affairs" shall be substituted by the words "Medicines

Authority"; and

(b) in sub-regulation (10) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority".

Amends regulation 7 of the principal regulations.

5. Regulation 7 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority";

(b) in sub-regulation (2) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur;

(c) in sub-regulation (4) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur; and

(d) sub-regulation (5) thereof shall be substituted by the following new sub-regulation:

"(5) The manufacturer or his authorised representative shall notify the Medicines Authority and the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in section2(c)(vii) of Schedule VII at the disposal of the Medicines Authority and the competent authorities of the other Member States concerned.".

Amends regulation 8 of the principal regulations.

6. Regulation 8 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof shall be substituted by the following new sub-regulation:

"Where it is found that the devices referred to in the definitions of "active implantable medical device" and "cusom device", correctly put into service and used in accordance with their intended purpose, may compromise the health and, or safety of patients, users or, where

applicable, other persons, all appropriate measures shall be taken by the Medicines Authority to withdraw such devices from the market or prohibit or restrict their being placed on the market or their being put into service.

The Medicines Authority shall immediately inform the Commission of any such measure, indicating the reasons for such decisions and, in particular, whether non-compliance with these regulations is due to:

(a) failure to meet the essential requirements referred to in regulation 5(1), where the device does not meet in full or in part the standards referred to in regulation 5(7);

(b) incorrect application of those standards;

(c) shortcomings in the standards themselves.";

(b) sub-regulation (2) thereof shall be substituted by the following new sub-regulation:

"(2) Where a device which does not comply bears the CE marking, the Medicines Authority shall take appropriate action against whomsoever has affixed the mark. The Medicines Authority shall inform the Commission and other Member States of such actions.";

(c) in sub-regulation (3) thereof, the words "Market Surveillance Directorate and the Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority";

(d) in sub-regulation (5) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur;

(e) sub-regulation (6) thereof shall be amended as follows:

(i) in paragraph (a) thereof, the words "Market Surveillance Directorate" shall be substituted by the words "Medicines Authority"; and

(ii) in paragraph (b) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority"; and

(f) sub-regulation (9) thereof shall be amended as follows:

(i) in paragraph (a) thereof, the words "Market Surveillance Directorate" shall be substituted by the words "Medicines Authority"; and

(ii) in paragraph (b) thereof, the words "Director of Market Surveillance" shall be substituted by the words "Medicines Authority".

Amends regulation 9 of the principal regulations.

7. In regulation 9 of the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur.

Amends regulation 10 of the principal regulations.

8. In regulation 10 of the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority".Amends regulation 11 of the principal regulations.

9. In regulation 11 of the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur.

Amends regulation 12of the principal regulations.

10. In regulation 12 of the principal regulations, the words "Market Surveillance Directorate" shall be substituted by the words "Medicines Authority".

Deletes regulation 13 of the principal regulations.

11. Regulation 13 of the principal regulations shall be deleted.

Amends Schedule IV to the principal regulations.

12. In paragraph (4) of Schedule IV to the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority".

Amends Schedule V to the principal regulations.

13. In paragraph (3) of Schedule V to the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority".

Amends Schedule VI to the principal regulations.

14. Schedule VI to the principal regulations shall be amended as follows:

(a) the words "Regulatory Affairs Directorate and Market Surveillance Directorate" shall be substituted by the words "Medicines Authority".

(b) in paragraph (5) of Schedule VI to the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority",

15. In paragraph (2) of Schedule VII to the principal regulations, the words "Market Surveillance Directorate, the Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority". Amends Schedule VII to the principal regulations.

16. In paragraph (7) of Schedule VIII the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur. Amends Schedule VIII to the principal regulations.

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