Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,454, 4 ta' Awwissu, 2020
Taqsima B

L.N. 318 of 2020

MEDICINES ACT
(CAP. 458)

In Vitro Diagnostic 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 *In Vitro* Diagnostic Medical Devices (Amendment) Regulations, 2020 and these regulations shall be read and construed as one with the *In Vitro* Diagnostic Medical Devices Regulations, hereinafter referred to as the " principal regulations". S.L. 427.16.

Amends regulation 1.2 of the principal regulations.

2. The proviso to sub-regulation 1.2 of the principal regulations shall be deleted.

Adds new regulation to the principal regulations.

3. (1) Regulations 3.1.9, 3.1.10, 3.1.11, 3.1.12, 3.1.13, 3.1.14, 3.1.14.1, 3.1.14.2, 3.1.14.3, 3.1.14.4, 3.1.15, 3.1.15.1, 3.1.16, 3.1.17, 3.1.18, 3.1.19, 3.1.20, 3.1.21, 3.1.22, 3.1.23, 3.1.24, 3.1.25.1, 3.1.25.2, 3.1.25.3 and 3.1.26 of the Regulations shall be numbered as 3.1.10, 3.1.11, 3.1.12, 3.1.13, 3.1.14, 3.1.15, 3.1.15.1, 3.1.15.2, 3.1.15.3, 3.1.15.4, 3.1.16, 3.1.16.1, 3.1.17, 3.1.18, 3.1.19, 3.1.20, 3.1.21, 3.1.22, 3.1.23, 3.1.24, 3.1.25, 3.1.26, 3.1.26.1, 3.1.26.2, 3.1.26.3 and 3.1.27 respectively; and

(2) Immediately after regulation 3.1.8.2 of the principal regulations there shall be added the following new regulation 3.1.9:

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

Amends regulation 8.1 of the principal regulations.

4. In regulation 8.1 of the principal regulations, the words "Director of Consumer Affairs" shall be substituted by the words "Medicines Authority".

Amends regulation 8.1.1 of the principal regulations.

5. Regulation 8.1.1 of the principal regulations shall be substituted by the following new regulation:

"8.1.1The Medicines Authority shall immediately inform Commission of any such measures, indicating the reasons for the decision and in particular, whether non-compliance is due to:".

Amends regulation 8.2 of the principal regulations.

6. In regulation 8.2 of the principal regulations shall be substituted by the following new regulation:

"8.2. Where a non-complying medical device referred to in regulation 3 bears the CE marking, the Medicines Authority shall take appropriate action against whomsoever has affixed the marking or drawn the declaration and shall so inform the Commission and the other Member States thereof.".

Amends regulation 8.4 of the principal regulations,

7. In regulation 8.4 of the principal regulations, the words "Director of Consumer Affairs" shall be substituted by the words "Medicines Authority".

Amends regulation 8.5 of the principal regulations.

8. In regulation 8.5 of the principal regulations, the words "Consumer and Industrial Goods Directorate of the Malta Standards Authority" shall be substituted by the words "Medicines Authority".

Amends regulation 9.1 of the principal regulations.

9. In regulation 9.1 of the principal regulations, the words "Consumer and Industrial Goods Directorate of the Malta Standards Authority" shall be substituted by the words "Medicines Authority".

Amends regulation 9.2 of the principal regulations.

10. In regulation 9.2 of the principal regulations, the words "Consumer and Industrial Goods Directorate of the Malta Standards Authority" shall be substituted by the words "Medicines Authority".

Amends regulation 9.3 of the principal regulations.

11. In regulation 9.3 of the principal regulations, the words "Consumer and Industrial Goods Directorate of the Malta Standards Authority" shall be substituted by the words "Medicines Authority".

Amends regulation 10.1 of the principal regulations.

12. In regulation 10.1 of the principal regulations, the words "Director of Consumer Affairs" shall be substituted by the words "Medicines Authority".

Amends regulation 10.3 of the principal regulations.

13. Regulation 10.3 of the principal regulations shall be substituted by the following new regulation:

"10.3. After carrying out an assessment, if possible together with the manufacturer, the Medicines Authority shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in regulation 10.1 for which appropriate measures, including possible withdrawal, have been taken or are contemplated.".

Amends regulation 10.4 of the principal regulations.

14. In regulation 10.4 of the principal regulations, the words "Consumer and Industrial Goods Directorate" shall be substituted by the words "Medicines Authority".

Amends regulation 10.5 of the principal regulations.

15. In regulation 10.5 of the principal regulations, the words "Consumer and Industrial Goods Directorate" shall be substituted by

the words "Medicines Authority".

16. In regulation 11.6.1 of the principal regulations, the words "Director of Consumer Affairs" shall be substituted by the words "Medicines Authority". Amends regulation 11.6.1 of the principal regulations.

17. In regulation 11.6.2 of the principal regulations, the words "Director of Consumer Affairs" shall be substituted by the words "Medicines Authority". Amends regulation 11.6.2 of the principal regulations.

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