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

L.N. 320 of 2020

MEDICINES ACT
(CAP. 458)

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 Medical Devices (Amendment) Regulations, 2020 and these regulations shall be read and construed as one with the Medical Devices Regulations hereinafter referred to as "the Regulations"..

S.L. 427.44.

Amends regulation 2 of the principal regulations.

2. In regulation 2 of the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority" wherever they occur.

Amends regulation 3of the principal regulations.

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

(a) the definitions "hip, knee and shoulder replacement", "Market Surveillance Directorate" and "Regulatory Affairs Directorate" shall be deleted; and

(b) immediately after the definition "medical device manufactured utilising tissues of animal origin" there shall be added the following new definition:

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

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Amends regulation 6 of the principal regulations.

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

(a) in sub-regulation (5) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority"; and

(b) in sub-regulation (12) thereof, the words "Head of the Regulatory Affairs Directorate" shall be substituted by the words

"Medicines Authority".

Amends regulation 7 of the principal regulations.

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

Amends regulation 8 of the principal regulations.

6. In sub-regulation (5) of regulation 8 of the principal regulations, the words "Regulatory Affairs Directorate" 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. Regulation 10 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof, the words "Director of Market Surveillance" shall be substituted by the words "Medicines Authority";

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

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

(d) in paragraph (b) of sub-regulation (5) thereof, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority";

(e) sub-regulation (8) thereof shall be substituted by the following new sub-regulation:

"(8) Where the Medicines Authority considers, in relation to a given product or group of products, that, in order to ensure the protection of health and safety and, or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, any necessary and justified transitional measures may be taken.

The Medicines Authority shall immediately inform the Commission and all other Member States of any

measures taken in pursuance of sub-regulations (1) to (10), giving the reasons for such decisions."; and

(f) sub-regulation (9) of the principal regulations shall be amended as follows:

(i) in paragraph (a) thereof, the words "Director of Market Surveillance" 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".

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

10. In sub-regulation (2) of regulation 12 of the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority". Amends regulation 12 of the principal regulations.

11. In regulation 13 of the principal regulations, the words "Regulatory Affairs Directorate" shall be substituted by the words "Medicines Authority". Amends regulation 13 of the principal regulations.

12. Sub-regulation (1) of regulation 14 of the principal regulations shall be substituted by the following new sub-regulation: Amends regulation 14 of the principal regulations.

"(1) Without prejudice to the existing national provisions and practices on medical secrets, the Medicines Authority shall ensure that all the parties involved in the application of these regulations are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of the Medicines Authority with regard to mutual information and the dissemination of warnings, nor the obligation of the persons concerned to provide information under criminal law.".

13. Regulation 15 of the principal regulations shall be deleted. Deletes regulation 15 of the principal regulations.

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