L.N. 321 of 2020

MEDICINES ACT
(CAP. 458)

Medical Devices and In-Vitro diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020

IN EXERCISE of the powers conferred by article 106(r) and (s) of the Medicines Act, the Minister responsible for Health, after consultation with the Medicines Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Medical Devices and In-Vitro diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020.

Interpretation.

2. For the purposes of these regulations, unless the context otherwise requires:

"Act" means the Medicines Act; Cap. 458.

"authorisation" means the approval given by the competent authority or any other authority as may from time to time be prescribed;

"competent authority" means the Medicines Authority as established under article 4 of the Medicines Act; Cap. 458.

"economic operator" means a manufacturer, an authorised representative, an importer or a distributor of medical devices;

"medical device" means any medical device as defined in paragraph 1 of Article 2 of Regulation (EU) 2017/745, and any in-vitro diagnostic medical device as defined in paragraph 2 of Article 2 of Regulation (EU) 2017/746 and shall include any product designated as such by the competent authority;

"Minister" means the Minister responsible for public health;

"premises" means the location of the storage of medical devices and in-vitro medical devices;

"public health" and "public health emergency" shall have the same meaning as assigned to them by article 2 of the Public Health Act; Cap. 465.

Cap. 465.

"public health risk" shall have the same meaning as assigned to it by article 2 of the Public Health Act;

"medical device registered person" means any person who is responsible for medical devices in terms of regulation 6;

"national medical device database" means the collection of data or other materials in relation to medical devices which are arranged in a systematic or methodical order and which are individually accessible by electronic or other means;

"non-conforming medical device" means any medical device that does not fulfill its specified requirements as required by or under these regulations or any other law;

Cap. 465.

"superintendent" means the Superintendent of Public Health as established by article 3 of the Public Health Act.

Designation of competent authority and accrediting body.

3. The competent authority is designated under these regulations:

(a) as the authority in charge of regulating and ensuring compliance and adherence to the applicable local and international laws that apply to medical devices; and

(b) as the authority responsible for designation and supervision of notified bodies concerned with medical devices in Malta.

Administration.

4. The administration of these regulations shall be vested in the Minister or such other person, agency or authority so delegated by the Minister for any of the purposes of these regulations.

Importation, wholesaling, manufacturing or re-purposing of medicinal devices.

5. (1) No person shall carry out importation, wholesaling, manufacturing or re-purposing in Malta of any medical device which is intended for trade within the European Union and, or the local market prior to obtaining all the necessary approvals, authorisations, licences, permits and, or any notification/s as required by or under these regulations or any other law.

(2) Any person intending to carry out any of the activities identified in sub-regulation (1) shall:

(a) comply with the provisions of these regulations;

(b) comply with all national and European Union regulations, including international obligations resulting from

any treaty to which Malta may from time to time be a part of, as may be applicable;

(c) obtain the necessary authorisation from the competent authority;

(d) possess the necessary qualifications and have undergone any necessary training as may be required by the competent authority;

(e) comply with any other applicable law;

(f) have a medical device registered person in Malta; and

(g) insert details of all medical devices which he markets locally in the national medical device database kept by the competent authority.

Obligation for medical device registered person.

6. (1) No person shall act as a medical device registered person responsible for any medical device locally unless they have registered as such with the competent authority.

(2) Any person who applies for registration as a medical device registered person shall satisfy any eligibility requirements as may be established by the competent authority.

(3) Any person registered as a medical device registered person with the competent authority shall be issued a registration document.

Issuing of approval.

7. (1) The issuing of any approval by the competent authority pursuant to these regulations shall be subject to:

(a) the submission by the applicant and the evaluation of documents, including due diligence documentation, and any other information as may be deemed necessary in order to ensure fulfilment of the authorisation requirements; and

(b) the attainment by the applicant of any authorisation, licence, permit, approval and clearance from the competent authority or any other entity as may be prescribed under these regulations or any other legislation that may be applicable from time to time:

Provided that the competent authority may, at its own discretion, request any additional information it deems necessary for the evaluation of the application.

(2) The withdrawal, revocation, cancellation or expiry of any

authorisation issued pursuant to these regulations shall preclude the holder thereof from carrying out the relevant activity.

Issue of guidelines.

8. The competent authority may issue guidelines and, or directives for establishing any other matter, including but not limited to the level of security considered necessary or expedient for the carrying out of any of the provisions of these regulations.

Monitoring and review of operations.

9. (1) The competent authority shall monitor and review any operations conducted within premises with a view to ensuring that any operation within the scope of these regulations is carried out in accordance with the provisions of these regulations and in compliance with any decision that may be lawfully taken pursuant to these regulations or any other applicable legislation.

(2) For the purposes of this regulation, the competent authority or any person so authorised shall have the right at all reasonable times and, where necessary, with the assistance of the Executive Police to enter and inspect any premises.

Obligation of economic operators to transmit complaints to competent authority.

10. (1) Any economic operator that has received complaints or reports from healthcare professionals, patients or users about incidents related to a medical device which they have made available on the local market, shall immediately forward this information to the competent authority.

(2) Every economic operator shall keep a register containing details of complaints, of non-conforming medical devices and of recalls and withdrawals of medical devices, and shall keep the competent authority informed of such monitoring.

(3) The competent authority may request any other information from any person or entity as it may deem necessary for the carrying out of its functions pursuant to these regulations.

Fines and penalties.

11. Any person who contravenes any provision of these regulations shall be guilty of an offence and shall on conviction be subject to a fine (*multa*) of not less than twelve thousand euro (€12,000) and not exceeding one hundred and twenty thousand euro (€120,000) or to imprisonment for a term not exceeding two (2) years, or to both such fine and imprisonment.

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