



LAWS OF MALAYSIA

Act 738

MEDICAL DEVICE AUTHORITY ACT 2012

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MEDICAL DEVICE AUTHORITY ACT 2012

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LAWS OF MALAYSIA**Act 738****MEDICAL DEVICE AUTHORITY ACT 2012**

An Act to provide for the establishment of the Medical Device Authority, to control and regulate medical device, the medical device industry and its activities, and to enforce the medical device laws, and for related matters.

[]

ENACTED by the Parliament of Malaysia as follows:

PART I**PRELIMINARY****Short title and commencement**

1. (1) This Act may be cited as the Medical Device Authority Act 2012.

(2) This Act comes into operation on a date to be appointed by the Minister by notification in the *Gazette*.

Interpretation

2. In this Act, unless the context otherwise requires—

“member” means a member of the Authority under section 4;

“committee” means a committee established under section 10;

“Fund” means the Fund established under section 23;

“Minister” means the Minister charged with the responsibility for health;

“Chairman” means the Director General of Health;

“Authority” means the Medical Device Authority established under section 3;

“appointed date” means the date appointed under subsection 1(2);

“medical device laws” means this Act and the Medical Device Act 2012 [Act 737], and includes any subsidiary legislation made under these laws.

PART II

THE AUTHORITY

Establishment of the Authority

3. (1) A body corporate with the name “Medical Device Authority” is established.

(2) The Authority shall have perpetual succession and a common seal.

(3) The Authority may sue and be sued in its name.

(4) Subject to and for the purposes of this Act, and upon such terms as it deems fit, the Authority may—

- (a) enter into contracts;
- (b) acquire, purchase, take, lease, hold, sell and enjoy movable and immovable property of every description; and
- (c) convey, assign, surrender, yield up, charge, mortgage, demise, reassign, transfer, or otherwise dispose of, or deal with any movable or immovable property or any interest in any movable or immovable property, vested in the Authority.

Membership of the Authority

4. (1) The Authority shall consist of the following members:

- (a) the Director General of Health as a Chairman;
- (b) the Chief Executive;
- (c) a representative of the Ministry of Finance;
- (d) a representative of the Ministry of Health; and
- (e) not more than five persons with expertise and experience in medical device matters to be appointed by the Minister.

(2) The provisions of the Schedule shall apply to the Authority.

(3) The Minister may amend the Schedule by order published in the *Gazette*.

Tenure of office

5. (1) Subject to such conditions as may be specified in his instrument of appointment, every member of the Authority appointed under paragraph 4(1)(e) shall, unless he sooner resigns or vacates his office or his appointment is sooner revoked, hold office for a term not exceeding three years.

(2) Every member of the Authority appointed under paragraph 4(1)(e) shall be eligible for reappointment but no member shall hold office for more than two consecutive terms.

Allowances

6. (1) The Chairman shall be paid such allowances as the Minister may determine after consultation with the Minister of Finance.

(2) All other members of the Authority, other than the Chief Executive, shall be paid such allowances as the Minister may determine after consultation with the Minister of Finance.

Chairman

7. (1) The Chairman of the Authority shall preside at all meetings of the Authority.

(2) In the absence of the Chairman for any reason, he shall appoint the Deputy of Director General of Health to carry out the duties of the Chairman.

Revocation of appointment and resignation

8. (1) The appointment of a member of the Authority, other than the members appointed under paragraphs 4(1)(a), (b), (c) and (d), may at any time be revoked by the Minister.

(2) A member, other than the Chief Executive, may at any time resign his office by a written notice addressed to the Minister.

Vacation of office

9. The office of a member of the Authority, other than Chief Executive, shall be vacated if—

- (a) he dies;
- (b) there has been proved against him, or he has been convicted of, a charge in respect of—
 - (i) an offence involving fraud, dishonesty or moral turpitude;
 - (ii) an offence under any law relating to corruption; or
 - (iii) any other offence punishable with imprisonment (in itself only or in addition to or in lieu of a fine) for more than two years;
- (c) his conduct, whether in connection with his duties as a member of the Authority or otherwise, has been such as to bring discredit to the Authority;
- (d) he becomes a bankrupt;

- (e) he is of unsound mind or is otherwise incapable of discharging his duties;
- (f) in the case of the Chairman, he absents himself from three consecutive meetings of the Authority without leave from the Minister;
- (g) in the case of a member of the Authority, other than the Chairman, he absents himself from three consecutive meetings of the Authority without leave of the Chairman;
- (h) his resignation is accepted by the Minister; or
- (i) his appointment is revoked by the Minister.

(2) Where a member appointed under paragraph 4(1)(e) ceases to be a member of the Authority, the Minister may appoint another person to fill the vacancy for the remainder of the term for which the vacating member was appointed in accordance with the provisions applying.

Committees

10. (1) The Authority may establish any committee it considers necessary or expedient to assist it in the performance of its functions under this Act.

(2) The Authority may elect any of its members to be the chairman of a committee established under subsection (1).

(3) The Authority may appoint any person to be a member of a committee.

(4) A member of a committee shall hold office for such term as may be specified in his letter of appointment and is eligible for reappointment.

(5) The Authority may, at any time, revoke the appointment of a member of a committee.

(6) A member of a committee may, at any time, resign his office by a written notice addressed to the chairman of the committee.

(7) The Authority may, at any time, discontinue the constitution or alter the composition of a committee.

(8) A committee may regulate its own procedure.

(9) A committee shall be subject to, and act in accordance with, any direction given to it by the Authority.

(10) Meetings of a committee shall be held at such times and places as the chairman of the committee may determine.

(11) A committee shall cause—

(a) minutes of all its meetings to be maintained and kept in proper form; and

(b) copies of the minutes of all its meetings to be submitted to the Authority as soon as practicable.

(12) A committee may invite any person to attend any of its meetings for the purpose of advising it on any matter under discussion but that person shall not be entitled to vote at the meeting.

(13) The members of a committee and any person invited under subsection (12) shall be paid such allowances and other expenses as the Authority may determine.

Disclosure of interest

11. (1) A member of the Authority or any committee established under section 10 who has or acquires a direct or indirect interest by himself, through a member of his family or his associate in relation to any matter under discussion by the Authority or committee, as the case may be, shall disclose to the Authority or committee, as the case may be, the fact of his interest and the nature of that interest.

(2) A disclosure under subsection (1) shall be recorded in the minutes of the meeting of the Authority or the committee, as the case may be, in which the matter is discussed and, after the disclosure the member—

(a) shall not be present or take part in any discussion or decision of the Authority or committee, as the case may be, about the matter; and

- (b) shall be disregarded for the purpose of constituting a quorum of the meeting of the Authority or committee, as the case may be,

when the matter is discussed or decided upon.

(3) A member of the Authority or committee who fails to disclose his interest as required under subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both.

(4) No act or proceedings of the Authority or committee shall be invalidated on the ground that any member of the Authority or committee has contravened this section.

(5) For the purposes of subsection (1)—

“a member of his family” includes—

- (a) his spouse;
- (b) his parent (including a parent of his spouse);
- (c) his child (including an adopted child or stepchild);
- (d) his brother or sister (including a brother or sister of his spouse); and
- (e) a spouse of his child, brother or sister; and

“associate” means—

- (a) a person who is a nominee or an employee of the member;
- (b) a firm of which the member or any nominee of his is a partner;
- (c) a partner of the member;
- (d) a trustee of a trust under which the member or a member of his family is a beneficiary; or
- (e) any corporation within the meaning of the Companies Act 1965 [Act 125], of which the member or any nominee of his or a member of the member’s family is a director or has a substantial shareholding in the corporation.

PART III

FUNCTIONS AND POWERS OF THE AUTHORITY

Functions and powers of the Authority

12. (1) The Authority shall have all the functions and powers imposed on it under the medical device laws and shall also have the following functions:

- (a) to implement and enforce and to consider and recommend reform to the medical device laws;
- (b) to regulate all matters relating to medical device and the medical device industry and its activities;
- (c) to encourage and promote the development of medical device and the medical device industry and its activities including in the area of research and training;
- (d) to provide consultancy and advisory service and any other services in relation to medical device and the medical device industry and its activities;
- (e) to utilize all the property of the Authority, movable and immovable, in such manner as the Authority may think expedient, including the raising of loans by mortgaging such property;
- (f) to impose fees or charges for services rendered by the Authority; and
- (g) to grant loans and scholarships to servants of the Authority for such purposes as may be approved by the Minister.

(2) The Authority shall have all such powers as may be necessary for, or in connection with, or incidental to, the performance of its functions under this Act.

Delegation of the Authority's functions and powers

13. (1) The Authority may, in writing, delegate any of its functions or powers other than its power to make subsidiary legislation, to—

- (a) the Chairman;
- (b) a member of the Authority; or
- (c) a committee.

(2) A member of the Authority or a committee, as the case may be, delegated with such function or power shall be bound to observe and have regard to all conditions and restrictions imposed by the Authority and all requirements, procedures and matters specified by the Authority.

(3) Any function and power delegated under this section shall be performed and exercised in the name and on behalf of the Authority.

(4) A delegation under this section shall not preclude the Authority itself from performing or exercising at any time any of the delegated functions and powers.

Power of Minister to give directions

14. (1) The Authority shall be responsible to the Minister.

(2) The Minister may, from time to time, give to the Authority directions of a general character consistent with the provisions of this Act relating to the performance of the functions and powers of the Authority and the Authority shall as soon as possible give effect to such directions.

Returns, reports, accounts and information

15. (1) The Authority shall furnish to the Minister such returns, reports, accounts and information with respect to its activities and finances as the Minister may from time to time require or direct.

(2) The returns, reports, accounts and information shall be in such form and shall contain such information relating to the proceedings and policy of the Authority and any other matter as the Minister may from time to time specify.

PART IV

OFFICERS AND SERVANTS OF THE AUTHORITY

Chief Executive

16. (1) The Minister shall appoint a person who has scientific qualification, technical knowledge of and experience in the field of medical device or medical device related matters to be the Chief Executive on such terms and conditions as he thinks desirable.

(2) In the absence of the Chief Executive for any reason, the Minister shall appoint an officer of the Authority to carry out the duties of the Chief Executive.

(3) The Authority shall vest in the Chief Executive any functions and powers of the Authority under this Act.

(4) The Chief Executive shall be responsible for the overall administration and management of the functions and the day-to-day affairs of the Authority.

(5) The Chief Executive shall have general control of the officers and servants of the Authority.

(6) The Chief Executive shall perform such other duties as the Minister or the Authority may direct.

Appointment of other officers and servants

17. (1) The Authority may employ such number of officers and servants as it thinks desirable and necessary and upon such terms and conditions as it considers appropriate for carrying out the purposes of the medical device laws.

(2) The Authority may, with the approval of the Minister, determine the conditions of service of its officers and servants.

Loans and advances

18. The Authority may grant loans and advances to its officers and servants for such purposes and on such terms and conditions as the Authority may determine.

Payment of retirement benefits, etc.

19. The Authority may make arrangements for the payment to its officers and servants and their dependents of such retirement benefits, gratuities and other allowances as the Authority may determine.

Authority may adopt regulations, etc.

20. The Authority may, with the approval of the Minister, adopt with such modifications as it deems fit any regulations, rules, policies, circulars and directives enacted or issued by the Federal Government in relation to any matter under this Part.

Employment

21. (1) The Authority shall, on the appointed date, accept into its employment every person who immediately before that date was in the employment or service of the Medical Device Bureau, Ministry of Health, Malaysia and who was given an option by the Government of Malaysia and had opted to serve as an employee of the Authority.

(2) Every such person who opted under subsection (1) to serve as an employee of the Authority shall be employed by the Authority on terms and conditions of service not less favourable than the terms and conditions of service to which he was entitled immediately before the appointed date.

(3) Until such time as the terms and conditions of service of its employees are drawn up by the Authority, the scheme and terms and conditions of service, including the law applicable to the conduct and discipline of employees of the Government, shall *mutatis mutandis* continue to apply to every person employed by the Authority under subsection (1).

(4) The Minister may, by order, make such modifications as may be necessary to the scheme and terms and conditions of service referred to in subsection (3) for the purpose of removing any difficulties as a consequence of the provisions of that subsection.

Continuation and completion of disciplinary proceedings

22. (1) Where on the appointed date any disciplinary proceedings is pending or existing against any employee of the Government who had opted to serve as an employee of the Authority, such proceedings shall be continued and completed by the Authority, and the law applicable to such employee immediately before the appointed date in relation to such proceedings shall apply to the proceedings continued and completed under this section.

(2) An order, ruling or direction made or given by a disciplinary authority of the Authority pursuant to this section shall in respect of such employee of the Government have the same force or effect as an order, ruling or direction made or given by the Disciplinary Authority, Disciplinary Board or Disciplinary Appeal Board, as the case may be, under the law referred to in subsection (1).

(3) The Minister may, by order, make such modifications to the law referred to in subsection (1) in their application to such employee of the Government as may be necessary for the purpose of removing difficulties as a consequence of the provision of subsection.

PART V

FINANCE

The Fund

23. (1) A fund to be known as the “Medical Device Authority Fund” is established and shall be administered and controlled by the Authority.

(2) The Fund shall consist of—

- (a) such sums as may be provided by Parliament, from time to time, for the purposes of this Act and the medical device laws;
- (b) all or any part of the registration, licence or other fees, administration charges, levies or other charges imposed by or payable to the Authority under the medical device laws;
- (c) all moneys derived as income from investments by the Authority;
- (d) all moneys derived from the sale, disposal, lease or hire of, or any other dealing with, any property, mortgages, charges or debentures vested in or acquired by the Authority;
- (e) all moneys earned from consultancy and advisory services and any other service provided by the Authority;
- (f) all other moneys and property which may in any manner become payable to or vested in the Authority in respect of any matter incidental to its functions and powers;

- (g) sums borrowed by the Authority under section 28; and
- (h) all other moneys lawfully received by the Authority.

Expenditure to be charged on the Fund

24. The Fund shall be expended for the following purposes:

- (a) paying any expenditure lawfully incurred by the Authority;
- (b) paying for the allowances and other expenses of the members of the Authority and members of committees and the remuneration, allowances and other expenses of the officers and servants of the Authority, including the granting of loans and advances, superannuation allowances, retirement benefits and gratuities;
- (c) paying any other expenses, costs, expenditure or other payments properly incurred or accepted by the Authority in the performance of its functions and the exercise of its powers under the medical device laws including the engagement of consultants, legal fees and costs and other charges and costs;
- (d) purchasing or hiring equipment, machinery and any other materials, acquiring land and any assets, and erecting buildings and carrying out any other works and undertakings in the performance of its functions and the exercise of its powers under the medical device laws;
- (e) repaying any moneys borrowed under section 28 and the interest due on the borrowed moneys; and
- (f) generally, paying any expenses for carrying into effect the provisions of the medical device laws.

Conservation of Fund

25. It shall be the duty of the Authority to conserve the Fund by so performing its function and exercising its powers under this Act as to secure that the total revenue of the Authority are sufficient to meet all sums properly chargeable to its revenue account including depreciation and interest on capital taking one year with another.

Expenditure and preparation of estimates

26. (1) The expenditure of the Authority up to such amount as may be authorized by the Minister for any one year shall be defrayed out of the Fund.

(2) Before 1 September each year, the Authority shall submit to the Minister an estimate of its expenditure, including the expenditure for research and development programmes, for the following year in such form and containing such particulars as the Minister may direct.

(3) The Minister shall, before 1 January the following year, notify the Authority of the amount authorized for expenditure generally or of the amount authorized for each description of expenditure based on the estimate prepared under subsection (2).

(4) The Authority may at any time submit to the Minister a supplementary estimate of its expenditure for any one year and the Minister may allow the whole or any part of the additional expenditure included therein.

Bank accounts

27. The Authority shall open and maintain an account or accounts with such financial institution or institutions in Malaysia as the Authority thinks fit, after consulting the Minister; and every such account shall be operated upon as far as practicable by cheques signed by any person or persons as may be authorized by the Authority for such purpose from time to time.

Power to borrow

28. The Authority may, from time to time, borrow in such form and at such rate of interest and for such period and upon such terms as to the time and method of repayment and otherwise, as may be approved by the Minister with the concurrence of the Minister of Finance, any money required by the Authority for meeting any of its obligations or discharging any of its functions.

Investment

29. The moneys of the Authority shall, in so far as they are not immediately required to be expended by the Authority under this Act, be invested in such manner as the Minister may, with the concurrence of the Minister of Finance, approve.

Financial procedure

30. Subject to this Act and the approval of the Minister, the Authority shall determine its own financial procedure.

Financial year

31. The financial year of the Authority shall begin on 1 January and end on 31 December of each year.

Accounts and reports

32. (1) The Authority shall cause proper accounts of the Fund and proper reports of its activities to be kept and shall, as soon as practicable after the end of each financial year, cause to be prepared for that financial year—

(a) a statement of accounts of the Authority which shall include a balance sheet and an account of income and expenditure; and

(b) a statement of its activities.

(2) The Authority shall cause the statement of accounts to be audited by independent auditors appointed by the Authority.

(3) The Authority shall as soon as possible send a copy of the statement of accounts certified by the auditors and a copy of the auditor's report to the Minister who shall cause such statement and report to be laid before both Houses of Parliament.

(4) The Statutory Bodies (Account and Annual Reports) Act 1980 [Act 240] shall apply to the Authority.

Payment to the Federal Consolidated Fund

33. The Authority shall on the instruction of the Federal Government, cause to be paid to the Federal Consolidated Fund an amount not exceeding twenty per cent of its current annual surplus after the fifth year of its operation.

PART VI**GENERAL****Institution of prosecution**

34. No prosecution shall be instituted for any offence under this Act without the consent in writing of the Public Prosecutor.

Public servant

35. The Chairman, members of the Authority and any of its committees, and all officers and agents of the Authority, while discharging their duties under this Act as the Chairman, such members, officers or agents, shall be deemed to be public servants within the meaning of the Penal Code [*Act 574*].

Public Authorities Protection Act 1948

36. The Public Authorities Protection Act 1948 [*Act 198*] shall apply to any action, suit, prosecution or proceedings against the Authority, any of its members, any member of a committee, or any officer or agent of the Authority in respect of any act, neglect or default done or committed by him in good faith or any omission omitted by him in good faith, in such capacity.

Obligation of secrecy

37. (1) Except for any purposes of this Act or for the purpose of any civil or criminal proceedings under any written law or where otherwise authorized by the Authority—

- (a) no member of the Authority or any of its committees or any officer or agent of the Authority or any person attending any meeting of the Authority or any of its

committees, whether during his tenure of office or during his employment or after that, shall disclose any information which has been obtained by him in the course of his duties and which is not published in pursuance of this Act; and

- (b) no other person who has by any means access to any information or document relating to the affairs of the Authority shall disclose such information or document.

(2) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both.

Representation in civil proceedings

38. Notwithstanding any other written law—

- (a) in any civil proceedings by or against the Authority; or
- (b) in any other civil proceedings in which the Authority is required or permitted by the court to be represented, or to be heard, or is otherwise entitled to be represented or to be heard,

any person authorized by the Authority for that purpose may, on behalf of the Authority, institute such proceedings or appear in such proceedings and may make all appearances and applications and do all acts in respect of the proceedings on behalf of the Authority.

Power to employ

39. The Authority may employ and pay agents, technical advisers and conformity assessment bodies, including advocates and solicitors, bankers, consultants and other persons, to transact any business or to do any act required to be transacted or done in the performance of its functions or for the better carrying into effect the purposes of this Act.

Regulations

40. The Minister may, after consultation with the Authority, make regulations as are necessary or expedient to give full effect or for carrying out the provisions of this Act.

Acts done in anticipation of the enactment of this Act

41. All acts done by any person or authority on behalf of the Authority in preparation for or in anticipation of the enactment of this Act and any expenditure incurred in relation thereto, shall be deemed to have been authorized by this Act, provided that the acts and things done are consistent with the general intention and purposes of this Act; and all rights or obligations acquired or incurred on as a result of the doing of those acts or things including any expenditure incurred in relation thereto, shall on the coming into operation of this Act, be deemed to be the rights and obligations of the Authority.

SCHEDULE

[Section 4]

Times and places of meetings

1. (1) The Authority is to hold as many meetings as are necessary for the efficient performance of its functions and such meetings are to be held at such places and times as the Chairman may decide, provided that the Chairman shall not allow more than two months to lapse between meetings.

(2) The Chairman shall call for a meeting if requested to do so in writing by the Minister or by at least two members of the Authority.

Quorum

2. The Chairman and four members of the Authority shall form a quorum at any meeting of the Authority.

Casting vote

3. If on any question to be determined by the Authority there is an equality of votes, the Chairman shall have a casting vote in addition to his deliberative vote.

Authority may invite others to meetings

4. (1) The Authority may invite any person to attend any meeting or deliberation of the Authority for the purpose of advising it on any matter under discussion, but any person so attending shall have no right to vote at the meeting or deliberation.

(2) A person invited under subparagraph (1) shall be paid such allowances as may be determined by the Authority.

Resolutions without meetings

5. (1) A resolution is taken to have been passed at a meeting of the Authority if—

(a) all members of the Authority have been informed of the proposed resolution, or reasonable efforts have been made to inform all members of the Authority of the proposed resolution; and

(b) without meeting, a majority of the members of the Authority indicate agreement with the resolution in accordance with the method determined by the Authority under subparagraph (2).

(2) Subparagraph (1) applies only if the Authority—

(a) decides that subparagraph (1) applies; and

(b) decides the method by which members of the Authority are to indicate agreement with resolutions.

Common seal

6. (1) The Authority shall have a common seal which shall bear such device as the Authority may approve and such seal may from time to time be changed, modified or made anew by the Authority as the Authority thinks fit.

(2) The common seal shall be kept in the custody of the Chief Executive or any other officer authorized by the Chief Executive, and shall be authenticated by the Chief Executive or by such other person authorized by the Chief Executive in writing.

(3) All deeds, documents and other instruments purported to be sealed with the common seal and authenticated in accordance with subsection (2), shall be deemed to have been validly executed until the contrary is proven.

(4) Notwithstanding subsection (3), any deed, document or instrument which, if executed by a person not being a body corporate, is not required to be under seal may in like manner be executed by an officer of the Authority authorized in that behalf.

(5) The common seal of the Authority shall be officially and judicially noticed.

Minutes

7. (1) The Authority and every committee shall cause minutes of all their meetings to be maintained and kept in proper form.

(2) A committee shall cause copies of the minutes of all its meetings to be submitted to the Authority as soon as practicable.

(3) Any minutes made of meetings of the Authority or a committee, if duly signed, shall be admissible in any legal proceedings as *prima facie* evidence of the facts stated in them without further proof.

(4) Every meeting of the Authority or committee in respect of the proceedings of which minutes have been so made in accordance with subparagraphs (1) and (2) shall be deemed to have been duly convened and held and all members at the meeting to have been duly qualified to act.

Procedure

8. The Authority may regulate its own procedure.

Validity of acts and proceedings

9. No act done or proceedings taken under this Act shall be questioned on the ground of—

- (a) any vacancy in the membership of, or any defect in the constitution of, the Authority; or
- (b) any omission, defect or irregularity not affecting the merits of the case.

Members to devote time to business of the Authority

10. The members of the Authority shall devote such time to the business of the Authority as is necessary to discharge their duties effectively.