

# THE STATUTES OF THE REPUBLIC OF SINGAPORE

# HEALTH SCIENCES AUTHORITY ACT 2001

#### 2020 REVISED EDITION

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# Health Sciences Authority Act 2001

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An Act to establish the Health Sciences Authority, to provide for its functions and powers, and for matters connected therewith.

[1 April 2001]

### PART 1

### PRELIMINARY

#### Short title

1. This Act is the Health Sciences Authority Act 2001.

#### Interpretation

- 2. In this Act, unless the context otherwise requires
  - "Authority" means the Health Sciences Authority established under section 3;
  - "Chairperson" means the Chairperson of the Authority and includes a temporary Chairperson appointed under section 8;
  - "Chief Executive" means the Chief Executive of the Authority, and includes any individual acting in that capacity;
  - "member" means a member of the Authority and includes a temporary member appointed under section 8.

[5/2018]

# PART 2

# ESTABLISHMENT, INCORPORATION AND CONSTITUTION OF AUTHORITY

# Establishment and incorporation of Health Sciences Authority

**3.** A body called the Health Sciences Authority is established, which is a body corporate with perpetual succession and a common seal and is by that name capable of --

- (a) suing and being sued;
- (*b*) acquiring, owning, holding and developing, or disposing of property, both movable and immovable; and
- (c) doing and suffering all such other acts or things as a body corporate may lawfully do and suffer.

# **Common seal**

**4.**—(1) The Authority must have a common seal and the seal may be broken, changed, altered or made anew as the Authority thinks fit.

(2) All deeds and other documents requiring the seal of the Authority must be sealed with the common seal of the Authority.

(3) All instruments to which the common seal is affixed must be signed by any 2 members generally or specially authorised by the Authority for the purpose or by one member and the Chief Executive.

(4) The Authority may, by resolution or otherwise in writing, appoint an officer of the Authority or any other agent either generally or in any particular case to execute or sign on behalf of the Authority any agreement or other instrument not under seal in relation to any matter coming within the powers of the Authority.

(5) All courts, judges and persons acting judicially are to take judicial notice of the common seal of the Authority affixed to any document and presume that it was duly affixed.

# **Constitution of Authority**

**5.**—(1) The Authority consists of —

- (a) a Chairperson; and
- (b) not less than 6 but not more than 10 other members,

all of whom must be appointed by the Minister.

(2) The Minister may appoint the Chief Executive to be a member of the Authority.

# Chairperson may delegate functions

6. The Chairperson may in writing authorise any member to exercise any power or perform any function conferred on the Chairperson by or under this Act.

# Term of office of members

7.—(1) A member of the Authority (including the Chairperson) holds office on such conditions and for such term not exceeding 3 years as the Minister specifies in the appointment, and may be re-appointed.

(2) Any member of the Authority may resign from his or her office at any time by giving at least one month's notice in writing to the Minister.

(3) The Minister may at any time revoke the appointment of any member as the Minister considers necessary in the interest of the effective performance of the functions of the Authority under this Act, or in the public interest.

(4) If a member dies or resigns or has his or her appointment revoked, the Minister may appoint any person to fill the vacancy for the remainder of the term for which the vacating member was appointed.

(5) The Authority is to pay to the Chairperson and other members of the Authority, out of the funds of the Authority, such salaries, fees and allowances as the Minister may determine.

# Temporary Chairperson and temporary members

**8.** The Minister may appoint any person as a temporary Chairperson or as a temporary member if the Chairperson or any member is absent from Singapore or for any other reason is unable to discharge his or her functions.

# Meetings and proceedings of Authority

9.—(1) At all meetings of the Authority, 5 members form a quorum.

(2) The Chairperson presides at all meetings of the Authority and, in his or her absence, the members present must elect one of their number to preside.

(3) Meetings of the Authority must be held at such times and places as the Chairperson may determine.

(4) All questions arising at any meeting must be decided by a majority of votes of the members present and voting.

(5) At any meeting of the Authority, the Chairperson or, in his or her absence, the member presiding at the meeting has a deliberative vote and, in the case of an equality of votes, he or she also has a casting vote.

(6) The validity of any proceedings of the Authority is not affected by any vacancy among its members or by any defect in the appointment of any member.

(7) Subject to the provisions of this Act and the Public Sector (Governance) Act 2018, the Authority may regulate its own proceedings.

[5/2018]

**10.** [*Repealed by Act 5 of 2018*]

#### PART 3

## FUNCTIONS, OBJECTS, DUTIES AND POWERS OF AUTHORITY

#### Functions, objects and duties of Authority

11.—(1) Subject to the provisions of this Act, the functions, objects and duties of the Authority are —

- (*a*) to regulate the manufacture, import, export, sale, supply, advertisement and use of health products, tobacco products, radioactive materials and irradiating apparatuses in accordance with the applicable written laws;
- (b) to conduct and advise the Government on technological assessments of health products for the purpose of

determining their quality, safety, efficacy and suitability for consumption and use in Singapore;

- (c) to collect and coordinate the collection of blood from donors and to test, process and distribute such blood and the products of such blood for the purpose of building and maintaining a safe and adequate national blood supply;
- (*d*) to provide professional, investigative, analytical and other services in health sciences and chemical metrology (relating to human health) to the Government and to any other person or body (whether in Singapore or elsewhere);
- (e) to conduct or engage any other person to conduct research in health sciences, and generally to promote the development of health sciences;
- (*f*) to act internationally as the national authority or representative of Singapore in respect of matters relating to health sciences; and
- (g) to carry out any other functions that are imposed upon the Authority by or under this Act or any other written law.

[15/2007; 54/2007]

(2) The Minister may give to the Authority any direction under section 5 of the Public Sector (Governance) Act 2018.

[5/2018]

(3) Nothing in this section is to be construed as imposing on the Authority, directly or indirectly, any form of duty or liability enforceable by proceedings before any court.

(4) In discharging its regulatory functions, the Authority must have regard to recognised international standards.

(5) In this section —

- "chemical metrology" means the science of achieving traceable analytical data in chemistry;
- "health product" means any substance, preparation or device that
  - (a) is represented for use by humans;

- (*b*) whether because of its presentation or otherwise, is likely to be taken for use by humans; or
- (c) is included in a class of substances, preparations or devices which are or are ordinarily intended for use by humans,

solely or principally for a therapeutic, preventive, palliative, diagnostic or cosmetic purpose, or any other purpose for the promotion or preservation of human health and wellbeing, including the following:

- (*d*) preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or the symptoms thereof, in humans;
- (e) compensating for any injury or handicap in humans;
- (f) investigating, modifying or replacing any part of the human anatomy or any physiological process in humans;
- (g) testing the susceptibility of humans to any disease, disorder or ailment;
- (*h*) influencing, controlling or preventing conception in humans;
- (*i*) testing for pregnancy in humans;
- (*j*) inducing anaesthesia in humans;
- (*k*) destroying or inhibiting micro-organisms that may be harmful to humans;
- (*l*) cleansing, fragrancing, deodorising, beautifying, preserving, improving, altering or restoring the complexion, skin, hair, nails or teeth of humans;
- "health sciences" includes forensic medicine, forensic science, clinical pharmacology, pharmaceutical science, radiation science, transfusion medicine and any other applied science or specialised scientific field that relates to human health;

"tobacco product" means any cigarette, cigar or any other form of tobacco which may be consumed through smoking, chewing or otherwise.

[15/2007; 30/2008]

# **Powers of Authority**

**12.** The Authority has power to do anything for the purpose of discharging its functions, objects and duties under this Act, or which is incidental or conducive to the discharge of those functions, objects or duties and, in particular, may —

- (a) enter into any contracts that may be necessary or expedient for the purpose of discharging its functions, objects or duties;
- (b) with the approval of the Minister, acquire and hold such movable or immovable property as may be necessary or expedient for carrying into effect the provisions of this Act and for the same purposes may sell, lease, mortgage, or otherwise alienate or dispose of any property so acquired;
- (c) with the approval of the Minister, form or participate in the formation of any company, partnership or joint venture as a shareholder or partner or in any other capacity and to share profits;
- (d) provide technical, consultancy, advisory or other services to the Government or to any other person or body in Singapore or elsewhere on any matter related to or connected with the functions, objects or duties of the Authority;
- (e) become a member or affiliate of any international body the functions, objects or duties of which are similar to those of the Authority;
- (*f*) charge fees or commissions for services rendered by the Authority or for the use of any of its facilities;
- (g) receive donations, grants, gifts, subsidies and contributions from any source, and raise funds by all lawful means;

- (h) publish or sponsor the publication of works concerning any matter related to the functions, objects or duties of the Authority;
- (i) grant loans to officers or employees of the Authority for any purposes specifically approved by the Authority as are likely to increase the efficiency of its officers or employees;
- (*j*) provide recreational facilities and promote recreational activities for, and activities conducive to, the welfare of officers or employees of the Authority and members of their families; and
- (k) provide training for employees of the Authority and to award scholarships or otherwise pay for such training.

[54/2007]

### Committees

**13.**—(1) The Authority may appoint committees consisting of one or more persons (whether members of the Authority or not) and define or vary the terms of reference of those committees.

(2) Subject to this Act and the Public Sector (Governance) Act 2018 and to the control of the Authority, each committee appointed under this section may regulate its procedure in such manner as the committee thinks fit.

[5/2018]

#### **Delegation of powers**

**14.**—(1) The Authority may, in respect of a specified matter or class of matters, by writing, delegate any of its powers to a member, officer or committee of the Authority.

(2) Every member, officer or committee purporting to act pursuant to a delegation under this section is, in the absence of proof to the contrary, presumed to be acting in accordance with the terms of the delegation.

#### PART 4

#### PROVISIONS RELATING TO STAFF

# Chief Executive, officers and employees, etc.

**15.**—(1) There must be a Chief Executive of the Authority, whose appointment, removal, discipline and promotion must be in accordance with the Public Sector (Governance) Act 2018.

[5/2018]

(2) The Authority may, subject to the Public Sector (Governance) Act 2018, appoint an individual to act temporarily as the Chief Executive during any period, or during all periods, when the Chief Executive —

- (a) is absent from duty or Singapore; or
- (b) is, for any reason, unable to perform the duties of the office.

[5/2018]

(3) The Authority may, subject to the Public Sector (Governance) Act 2018, appoint and employ, on such terms and conditions as it may determine, such other officers, employees, consultants and agents as may be necessary for the effective performance of its functions.

[5/2018]

#### Protection from personal liability

**16.**—(1) No suit or other legal proceedings shall lie personally against any member, officer or employee of the Authority or other person acting under the direction of the Authority for anything which is in good faith done or intended to be done in the execution or purported execution of this Act or any other written law.

(2) Where the Authority provides a service to the public by which information is supplied to the public, neither the Authority nor any of its members, officers or employees involved in the supply of such information shall be liable for any loss or damage suffered by any member of the public by reason of any error or omission of whatever nature appearing in the information or however caused if made in good faith and in the ordinary course of the discharge of the duties of such members, officers or employees.

**17.** [*Repealed by Act 5 of 2018*]

# PART 5

# FINANCIAL PROVISIONS

# **Financial year**

**18.** The financial year of the Authority begins on 1 April of each year and ends on 31 March of the succeeding year.

# Estimates

**19.** A summary of the annual estimates and supplementary estimates adopted by the Authority must be published in the *Gazette*.

# **Funds of Authority**

20. The funds of the Authority consist of —

- (a) all moneys transferred to the Authority under section 30;
- (b) all moneys received by the Authority by way of grants or subsidies;
- (c) all gifts, donations and contributions to the Authority;
- (*d*) all fees, charges, commissions, rents, interests, dividends and other income accruing to the Authority;
- (e) all moneys borrowed by the Authority under this Act;
- (f) all moneys recovered or collected by the Authority or any officer or employee of the Authority (including sums collected for the composition of offences) under this Act or any other written law administered by the Authority; and
- (g) all other moneys lawfully received by the Authority for the purposes of the Authority.

# Grants-in-aid

**21.** For the purpose of enabling the Authority to carry out its functions under this Act, the Minister may make grants-in-aid to the Authority of such sums of money, as the Minister may determine, out of moneys to be provided by Parliament.

# **Borrowing powers**

**22.** The Authority may for the purposes of this Act raise loans from the Government or, with the consent of the Minister, from any other source.

# Issue of shares, etc.

**22A.** As a consequence of the vesting of any property, rights or liabilities of the Government in the Authority under this Act, or of any capital injection or other investment by the Government in the Authority in accordance with any written law, the Authority must issue such shares or other securities to the Minister for Finance as that Minister may direct.

# **Bank** accounts

**23.** The Authority must open and maintain one or more accounts with such bank or banks as the Authority thinks fit and every such account must be operated by such person or persons authorised to do so by the Authority.

# **Application of funds**

**24.** The funds of the Authority must be applied only in payment or discharge of the expenses, obligations and liabilities of the Authority and in making any payment that the Authority is authorised or required to make.

# **Power of investment**

**25.** The Authority may invest its funds in accordance with the standard investment power of statutory bodies as defined in section 33A of the Interpretation Act 1965.

[45/2004]

**26.** [*Repealed by Act 5 of 2018*]

**27.** [*Repealed by Act 5 of 2018*]

**28.** [*Repealed by Act 5 of 2018*]

**29.** [*Repealed by Act 5 of 2018*]

# PART 6

# TRANSFER OF PROPERTY, ASSETS, LIABILITIES AND EMPLOYEES

#### Transfer to Authority of property, assets and liabilities

**30.**—(1) As from 1 April 2001, such movable and immovable property vested in the Government as may be determined by the Minister for Finance and used or managed by any of the departments as specified in the Schedule and all assets, interests, rights, privileges, liabilities and obligations of the Government relating to any such department are transferred to and vest in the Authority without further assurance, act or deed.

(2) If any question arises as to whether any particular property, or whether any particular asset, interest, right, privilege, liability or obligation has been transferred to or vested in the Authority under subsection (1), a certificate under the hand of the Minister for Finance is conclusive evidence that the property, asset, interest, right, privilege, liability or obligation was or was not so transferred or vested.

(3) Any immovable property to be transferred to and vested in the Authority under subsection (1) is held by the Authority upon such tenure and subject to such terms and conditions as the President may determine.

# **Transfer of employees**

**31.**—(1) As from 1 April 2001, such persons or categories of persons as the Minister may determine who, immediately before that date, were employed by the Government in any of the departments as specified in the Schedule are transferred to the service of the Authority on terms no less favourable than those enjoyed by them immediately prior to their transfer.

(2) If any question arises as to whether any person or category of persons has been transferred to the service of the Authority under subsection (1), a certificate under the hand of the Minister is conclusive evidence that the person or category of persons was or was not transferred.

(3) Until such time as terms and conditions of service are drawn up by the Authority, the scheme and terms and conditions of the Government continue to apply to every person transferred to the service of the Authority under subsection (1) as if the person were still in the employment of the Government.

# Pension rights, etc., of Government employees to be preserved

**32.**—(1) The terms and conditions to be drawn up by the Authority must take into account the terms and conditions of service (including salaries and accrued rights to leave) enjoyed by the persons transferred to the service of the Authority under section 31 while in the employment of the Government.

(2) Any term or condition relating to the length of service with the Authority must recognise the length of service of the persons so transferred while in the employment of the Government to be service with the Authority.

(3) Nothing in the terms and conditions to be drawn up by the Authority is to adversely affect the conditions that would have been applicable to persons transferred to the service of the Authority as regards any pension, gratuity or allowance payable under the Pensions Act 1956.

(4) Where a person has been transferred to the service of the Authority under section 31, the Government is liable to pay to the Authority such portion of any pension, gratuity or allowance payable to the person on his or her retirement as the same bears to the proportion which the aggregate amount of the person's pensionable emoluments during his or her service with the Government bears to the aggregate amount of the person's pensionable emoluments during his or her service under both the Government and the Authority.

(5) Where any person in the service of the Authority, whose case does not fall within the scope of any pension or other schemes established under this section, retires or dies in the service of the Authority or is discharged from such service, the Authority may grant to that person or to such other person or persons wholly or partly dependent on that person, as the Authority thinks fit, such allowance or gratuity as the Authority may determine.

# No benefits in respect of abolition or reorganisation of office

**33.** Despite the provisions of the Pensions Act 1956, no person who is transferred to the service of the Authority under section 31 is entitled to claim any benefit under that Act on the ground that he or she has been retired from the service of the Government on account of abolition or reorganisation of office in consequence of the establishment and incorporation of the Authority.

# **Existing contracts**

**34.** All deeds, contracts, schemes, bonds, agreements, instruments and arrangements, subsisting immediately before 1 April 2001 to which the Government is a party and which relates to any of the departments specified in the Schedule or to any person transferred to the service of the Authority under section 31 continue in force on and after that date and are enforceable by or against the Authority as if the Authority had been named therein or had been a party thereto instead of the Government.

# Continuation and completion of disciplinary and other legal proceedings

**35.**—(1) Where on 1 April 2001, any disciplinary proceedings were pending against any employee of the Government transferred to the service of the Authority, the proceedings must be carried on and completed by the Authority.

(2) Where on 1 April 2001, any matter was in the course of being heard or investigated or had been heard or investigated by a committee acting under due authority but no order, ruling or decision had been made on the matter, the committee must complete the hearing or investigation and must make an order, ruling or direction that it could have made under the authority vested in it before that date.

(3) Any order, ruling or direction made by a committee pursuant to this section is to be treated as an order, a ruling or a direction of the Authority and has the same force or effect as if it had been made by the Authority pursuant to the authority vested in the Authority under this Act.

(4) All proceedings or causes of action pending or existing immediately before 1 April 2001 by or against the Government in respect of any of the departments specified in the Schedule may be continued, completed and enforced by or against the Authority.

#### Misconduct or neglect of duty by employee before transfer

**36.** The Authority may reprimand, reduce in rank, retire, dismiss or punish in some other manner a person who had, while he or she was in the employment of the Government, been guilty of any misconduct or neglect of duty which would have rendered him or her liable to be reprimanded, reduced in rank, retired, dismissed or punished in some other manner if he or she had continued to be in the employment of the Government and if this Act had not been enacted.

# PART 7

### MISCELLANEOUS

**37.** [*Repealed by Act 5 of 2018*]

#### Symbol or representation of Authority

**38.**—(1) The Authority has the exclusive right to the use of such symbol or representation as it may select or devise and thereafter display or exhibit the symbol or representation in connection with its activities or affairs.

(2) Any person who uses a symbol or representation identical with that of the Authority, or which so resembles the Authority's symbol or representation as to deceive or cause confusion, or to be likely to deceive or to cause confusion, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 6 months or to both.

#### **Preservation of secrecy**

**39.**—(1) Except for the purpose of the performance of his or her duties or the exercise of his or her functions or when lawfully required to do so by any court or where required or allowed by any written law, a person who is or has been a member, an officer, an employee or an agent of the Authority or a member of a committee of

the Authority must not disclose any information relating to the affairs of the Authority or of any other person which has been obtained by him or her in the performance of his or her duties or the exercise of his or her functions.

[5/2018]

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 12 months or to both.

# **Composition of offences**

**40.**—(1) The Chief Executive or any officer authorised by the Chief Executive may compound any offence under this Act that is prescribed as a compoundable offence by collecting from a person reasonably suspected of having committed the offence a sum of money not exceeding \$1,000.

(2) On payment of the sum of money, no further proceedings are to be taken against that person in respect of the offence.

# Regulations

**41.** The Authority may, with the approval of the Minister, make regulations for any or both of the following purposes:

- (*a*) regulating the proceedings of the Authority or of the committees of the Authority;
- (b) providing for or prescribing any matters which are necessary or convenient to be provided for or prescribed for carrying out or giving effect to the provisions of this Act.

# Saving

**42.** Insofar as it is necessary to preserve the effect of any document issued by or relating to any of the departments specified in the Schedule, any reference in such document to any such department is to be construed as a reference to the Authority.

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# THE SCHEDULE

Sections 30(1), 31(1), 34, 35(4) and 42

#### DEPARTMENTS

- 1. Institute of Science and Forensic Medicine
- 2. Singapore Blood Transfusion Service
- 3. National Pharmaceutical Administration
- 4. Centre for Drug Evaluation
- 5. Product Regulation Department

# LEGISLATIVE HISTORY HEALTH SCIENCES AUTHORITY ACT 2001

This Legislative History is a service provided by the Law Revision Commission on a best-efforts basis. It is not part of the Act.

#### 1. Act 4 of 2001 — Health Sciences Authority Act 2001

Bill	:	3/2001
First Reading	:	12 January 2001
Second and Third Readings	:	22 February 2001
Commencement	:	1 April 2001

2. Act 5 of 2002 — Statutory Corporations (Capital Contribution) Act 2002 (Amendments made by section 3 read with item (11) of the Schedule to the above Act)

Bill	:	7/2002
First Reading	:	3 May 2002
Second and Third Readings	:	24 May 2002
Commencement	:	15 July 2002 (section 3 read with item (11) of the Schedule)

#### 3. 2002 Revised Edition — Health Sciences Authority Act (Chapter 122C)

Operation : 31 July 2002

#### 4. Act 45 of 2004 — Trustees (Amendment) Act 2004

(Amendments made by section 25(4) read with item (15) of the Schedule to the above Act)

Bill	:	43/2004
First Reading	:	21 September 2004
Second and Third Readings	:	19 October 2004
Commencement	:	15 December 2004 (section 25(4) read with item (15) of the Schedule)

#### 5. Act 27 of 2007 — Radiation Protection Act 2007

(Amendments made by section 46 read with item (2) of the Second Schedule to the above Act)

Bill	:	14/2007
First Reading	:	9 April 2007

Second and Third Readings	:	21 May 2007
Commencement	:	1 July 2007 (section 46 read with item (2) of the Second Schedule)

#### 6. Act 15 of 2007 — Health Products Act 2007

(Amendments made by section 77 of the above Act)

Bill	:	3/2007
First Reading	:	22 January 2007
Second and Third Readings	:	12 February 2007
Commencement	:	1 November 2007 (section 77)

#### 7. Act 54 of 2007 — Agency for Science, Technology and Research (Amendment) Act 2007

(Amendments made by section 6(1) of the above Act)

Bill	:	45/2007
First Reading	:	22 October 2007
Second and Third Readings	:	12 November 2007
Commencement	:	1 January 2008 (section 6(1)( <i>a</i> ) and ( <i>c</i> ))

# 8. Act 30 of 2008 — Statutes (Miscellaneous Amendments) (No. 2) Act 2008

(Amendments made by section 7 of the above Act)

Bill	:	27/2008
First Reading	:	15 September 2008
Second and Third Readings	:	17 November 2008
Commencement	:	17 December 2008 (section 7)

#### 9. Act 5 of 2018 — Public Sector (Governance) Act 2018

(Amendments made by section 66 of the above Act)

Bill	:	45/2017
First Reading	:	6 November 2017
Second Reading	:	8 January 2018
Notice of Amendments	:	8 January 2018
Third Reading	:	8 January 2018
Commencement	:	1 April 2018 (section 66)

# Abbreviations

C.P.	Council Paper	
G.N. No. S (N.S.)	Government Notification Number Singapore (New Series)	
G.N. No.	Government Notification Number	
G.N. No. S	Government Notification Number Singapore	
G.N. Sp. No. S	Government Notification Special Number Singapore	
L.A.	Legislative Assembly	
L.N.	Legal Notification (Federal/Malaysian Subsidiary Legislation)	
M. Act	Malayan Act/Malaysia Act	
M. Ordinance	Malayan Ordinance	
Parl.	Parliament	
S.S.G.G. (E) No.	Straits Settlements Government Gazette (Extraordinary) Number	
S.S.G.G. No.	Straits Settlements Government Gazette Number	

# COMPARATIVE TABLE HEALTH SCIENCES AUTHORITY ACT 2001

This Act has undergone renumbering in the 2020 Revised Edition. This Comparative Table is provided to help readers locate the corresponding provisions in the last Revised Edition.

2020 Ed.	2002 Ed.
	<b>14</b> —(3) [Deleted by Act 5 of 2018]
	<b>19</b> —(1) [Deleted by Act 5 of 2018]
	(2) [Deleted by Act 5 of 2018]
	(3) [Deleted by Act 5 of 2018]
19	(4)