



# **Therapeutic Goods and Other Legislation Amendment Act 2002**

**No. 56, 2002**

**An Act to amend the law relating to therapeutic  
goods and industrial chemicals, and for related  
purposes**

Note: An electronic version of this Act is available in SCALEplus  
(<http://scaleplus.law.gov.au/html/comact/browse/TOCN.htm>)



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**An Act to amend the law relating to therapeutic  
goods and industrial chemicals, and for related  
purposes**

*[Assented to 3 July 2002]*

The Parliament of Australia enacts:

## **1 Short title**

This Act may be cited as the *Therapeutic Goods and Other  
Legislation Amendment Act 2002*.

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## 2 Commencement

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, on the day or at the time specified in column 2 of the table.

<b>Commencement information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provision(s)</b>	<b>Commencement</b>	<b>Date/Details</b>
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day on which this Act receives the Royal Assent	3 July 2002
2. Schedule 1, items 6 and 7	The later of: (a) immediately after item 5 of Schedule 1 to this Act commences; and (b) immediately after Schedule 1 to the <i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i> commences	4 October 2002 (paragraph (b) applies)
3. Schedule 3, item 3	On the day on which this Act receives the Royal Assent, subject to subsection (3)	3 July 2002
4. Schedule 3, item 4	Immediately after item 22 of Schedule 3 commences, subject to subsection (3)	4 October 2002
5. Schedule 3, item 5	On the day on which this Act receives the Royal Assent, subject to subsection (4)	Does not commence at all
6. Schedule 3, item 22	Immediately after Schedule 1 to the <i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i> commences, subject to subsection (3)	4 October 2002
7. Schedule 4, item 1	Immediately after Schedule 1 to the <i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i> commences	4 October 2002
8. Schedule 4, item 2	On the day on which this Act receives the Royal Assent, subject to subsection (5)	3 July 2002

Note: This table relates only to the provisions of this Act as originally passed by the Parliament and assented to. It will not be expanded to deal with provisions inserted in this Act after assent.

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- (2) Column 3 of the table is for additional information that is not part of this Act. This information may be included in any published version of this Act.
  - (3) If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences before this section, items 3, 4 and 22 of Schedule 3 to this Act do not commence at all.
  - (4) If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* does not commence before this section, item 5 of Schedule 3 to this Act does not commence at all.
  - (5) If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences before this section, item 2 of Schedule 4 to this Act does not commence at all.

### **3 Schedule(s)**

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

## Schedule 1—Therapeutic goods (cooperative scheme)

### *Therapeutic Goods Act 1989*

#### **1 Subsection 3(1)**

Insert:

*Commonwealth authority* includes:

- (a) a body corporate, or an unincorporated body, established for a public purpose by or under an Act; and
- (b) a tribunal or authority established by or in accordance with an Act.

#### **2 Subsection 3(1)**

Insert:

*Commonwealth officer* includes:

- (a) a Minister; and
- (b) a person holding:
  - (i) an office established by or under an Act; or
  - (ii) an appointment made under an Act; or
  - (iii) an appointment made by the Governor-General or a Minister but not under an Act; and
- (c) a person who is a member or officer of a Commonwealth authority; and
- (d) a person who is in the service or employment of the Commonwealth, or of a Commonwealth authority, or is employed or engaged under an Act or regulations made under an Act.

#### **3 Subsection 3(1)**

Insert:

*State* includes the Australian Capital Territory and the Northern Territory.

#### **4 After subsection 3(7)**

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Insert:

- (7A) For the purposes of this Act, a corresponding State law *imposes a duty* on a Commonwealth officer or Commonwealth authority if:
- (a) the corresponding State law confers a function or power on the officer or authority; and
  - (b) the circumstances in which the function or power is conferred give rise to an obligation on the officer or authority to perform the function or to exercise the power.

## **5 Section 6A**

Repeal the section, substitute:

### **6AAA Commonwealth consent to conferral of functions etc. on its officers and authorities by corresponding State laws**

- (1) A corresponding State law may confer functions or powers, or impose duties, on:
  - (a) a Commonwealth officer; or
  - (b) a Commonwealth authority.
- (2) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:
  - (a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on Commonwealth officers or Commonwealth authorities; or
  - (b) the authorisation would otherwise exceed the legislative power of the Commonwealth.
- (3) Subsection (1) does not extend to a function, power or duty of a kind specified in regulations made for the purposes of this subsection.
- (4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on a Commonwealth officer or Commonwealth authority to the extent to which that law:
  - (a) is consistent with subsections (1) to (3); and
  - (b) is capable of operating concurrently with this Act.

## 6AAB When duty imposed

### *Application*

- (1) This section applies if a corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority.

### *State legislative power sufficient to support duty*

- (2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:
  - (a) imposing the duty is within the legislative powers of the State concerned; and
  - (b) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 6AAA to the imposition of the duty by the corresponding State law).

### *Commonwealth legislative power sufficient to support duty but State legislative powers are not*

- (3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.
- (4) If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.
- (5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:
  - (a) is within the legislative powers of the Commonwealth; and
  - (b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

- (6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing such a duty would:
  - (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
  - (b) otherwise exceed the legislative power of the Commonwealth.
- (7) Subsections (1) to (6) do not limit section 6AAA.

### **6AAC Imposing duty under State law**

- (1) This section:
  - (a) applies only for the purposes of the application of the provisions of this Act or another law of the Commonwealth (with or without modification) as a law of a State by a provision of a corresponding State law; and
  - (b) does not apply for those purposes if the corresponding State law otherwise provides.
- (2) If the corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority to do a particular thing, the duty is taken to be imposed by the corresponding State law to the extent to which imposing the duty:
  - (a) is within the legislative powers of the State; and
  - (b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.
- (3) To avoid doubt, the corresponding State law does not impose the duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing the duty would:
  - (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
  - (b) otherwise exceed the legislative powers of the State.
- (4) If imposing on the Commonwealth officer or Commonwealth authority the duty to do that thing would:

- (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
  - (b) otherwise exceed the legislative powers of both the State and the Commonwealth;
- the corresponding State law is taken instead to confer on the officer or authority a power to do that thing at the discretion of the officer or authority.

**6AAD Conferral of jurisdiction on federal courts**

If:

- (a) a provision of a corresponding State law purports to apply a provision of a law of the Commonwealth (the *applied provision*) as a law of the State; and
  - (b) the applied provision purports to confer jurisdiction in relation to a matter on a federal court;
- the jurisdiction in relation to that matter is taken to be conferred on the court by this section.

**6AAE Consequences of State law conferring duty, function or power on Commonwealth officer or Commonwealth authority**

- (1) If a corresponding State law confers on a Commonwealth officer or Commonwealth authority:
  - (a) the function of including goods in the Register; or
  - (b) the power to include goods in the Register;the officer or authority may include the goods in the Register in accordance with the corresponding State law.
- (2) If a corresponding State law authorises or requires a Commonwealth officer or Commonwealth authority to cancel the inclusion of goods in the Register, the officer or authority may cancel the inclusion of the goods in the Register in accordance with the corresponding State law.
- (3) The inclusion of goods in the Register under subsection (1) does not subject any person to any liability whatever under this Act, except a liability under Part 5.
- (4) A Commonwealth officer or Commonwealth authority may make any notations in the Register that the officer or authority considers

necessary to identify entries that relate to goods included in the Register under subsection (1).

- (5) Goods may be included in the Register under subsection (1) even though the same goods have already been included in the Register under another provision of this Act.
- (6) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods:
  - (a) in the part of the Register for goods known as registered goods; or
  - (b) in the part of the Register for goods known as listed goods.

**6 Subsection 6AAE(3)**

Omit “Part 5”, substitute “Part 6-1”.

**7 At the end of subsection 6AAE(6)**

Add:

; or (c) in the part of the Register for medical devices included under Chapter 4.

## Schedule 2—Industrial chemicals

### *Industrial Chemicals (Notification and Assessment) Act 1989*

#### **1 Section 5 (definition of *Chairperson*)**

Repeal the definition.

#### **2 Section 5 (definition of *Chief Executive Officer*)**

Repeal the definition.

#### **3 Section 5 (definition of *Commission*)**

Repeal the definition.

#### **4 Subsection 91(2)**

Omit “Chief Executive Officer”, substitute “Secretary of the Department”.

#### **5 Subsection 91(3)**

Repeal the subsection, substitute:

- (3) The Secretary of the Department may require the Director to perform functions or carry out duties for the Department in relation to chemicals to the extent to which they do not interfere with the performance of functions referred to in subsection (1) or (2).

#### **6 Subsection 99(1)**

Repeal the subsection, substitute:

- (1) The Secretary of the Department may make the services of employees in the Department available for the purposes of assessing chemicals under this Act or assisting in the administration of this Act.

Note: The heading to section 99 is altered by omitting “**Commission**” and substituting “**Department**”.

#### **7 Subsection 99(3)**

Repeal the subsection, substitute:

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- (3) The functions or duties of the Director referred to in subsection 91(3) may be functions or duties relating to the control of employees in the Department referred to in subsection (1) of this section while they are performing functions and duties for the Department.

**8 Subsection 100(1)**

Omit “Chairperson”, substitute “Secretary of the Department”.

**9 At the end of Part 5**

Add:

**100A Industrial Chemicals Account**

- (1) The Industrial Chemicals Account is established.
- (2) The Account is a Special Account for the purposes of the *Financial Management and Accountability Act 1997*.

**100B Credits to Account**

- (1) There must be credited to the Account the following:
- (a) all money appropriated by the Parliament for the purposes of the Account;
  - (b) any amount of registration charge or amount on account of registration charge paid under section 80F, 80K or 80S;
  - (c) any registration charge actually paid on an assessment under section 80QA or on a reconsideration or review of such an assessment;
  - (d) any fees received under subsection 110(1);
  - (e) amounts equal to amounts received by the Commonwealth in connection with the performance of the Director’s functions under this Act or the regulations;
  - (f) amounts equal to money received by the Commonwealth for services provided or to be provided, by or on behalf of the Commonwealth, using money from the Account;
  - (g) amounts equal to interest received by the Commonwealth from the investment of money from the Account;
  - (h) amounts equal to money received by the Commonwealth in relation to property paid for with money from the Account;

- (i) amounts equal to amounts of any gifts given or bequests made for the purposes of the Account;
  - (j) amounts equal to receipts relating to the recovery of debts (other than debts in respect of statutory fines and penalties) by the Commonwealth that are associated with expenditure of money from the Account;
  - (k) an amount equal to the sum of the amounts that:
    - (i) were payable to the National Occupational Health and Safety Commission under section 58A of the *National Occupational Health and Safety Commission Act 1985*; and
    - (ii) had not been paid to the Commission before this section commences;
  - (l) amounts payable under subsection (2).
- (2) The National Occupational Health and Safety Commission must pay to the Commonwealth an amount equal to the sum of the amounts that:
- (a) were paid to the Commission, under section 58A of the *National Occupational Health and Safety Commission Act 1985*, before this section commences; and
  - (b) have not been expended by the Commission.

### **100C Purposes of the Account**

- (1) The purposes of the Account are to make payments:
- (a) to further the object of this Act (as set out in section 3); and
  - (b) without limiting paragraph (a):
    - (i) to enable the Director to perform functions under this Act and the regulations; and
    - (ii) to enable the Director to make payments, on behalf of the Commonwealth, under Part 3A; and
  - (c) to enable the Commonwealth to participate:
    - (i) in the international harmonisation of regulatory controls or standards on industrial chemicals and other related activities; and
    - (ii) the development of international agreements and arrangements in relation to industrial chemicals; and
  - (d) otherwise in connection with the performance of the Director's functions under this Act or the regulations; and



- (e) to reimburse the National Occupational Health and Safety Commission for amounts expended by the Commission, or to allow the Commission to meet obligations incurred, before the commencement of this section for the purposes of:
  - (i) enabling the Director of Chemicals Notification and Assessment to perform functions under this Act or the regulations; or
  - (ii) enabling the Director to make payments, on behalf of the Commonwealth, under Part 3A.
- (2) Without limiting paragraph (1)(d), payments in connection with the performance of the Director's functions under this Act or the regulations include payments in connection with litigation, administrative review or other proceedings in relation to the performance of those functions.

***National Occupational Health and Safety Commission Act  
1985***

**10 Subsection 8(2A)**

Repeal the subsection.

**11 Section 58A**

Repeal the section.

**12 Section 59**

Omit “, or for application as described in subsection 58A(2),”.

## Schedule 3—Therapeutic goods (conformity assessments)

### *Therapeutic Goods Act 1989*

#### **1 Subsection 3(1) (definition of *approved conformity assessment body*)**

Repeal the definition.

#### **2 Subsection 3(1) (definition of *conformity assessment body*)**

Repeal the definition.

#### **3 Subsection 3(1) (definition of *conformity assessment certificate*)**

Repeal the definition.

Note: If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences before section 2 of this Act, this item does not commence at all. See subsection 2(3) of this Act.

#### **4 Subsection 3(1)**

Insert:

*conformity assessment certificate* means a certificate issued under section 41EE.

Note: If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences before section 2 of this Act, this item does not commence at all. See subsection 2(3) of this Act.

#### **5 Subsection 3(1) (definition of *conformity assessment certificate*)**

Repeal the definition, substitute:

*conformity assessment certificate* means a certificate issued under section 41EE.

Note: If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* does not commence before section 2 of this Act, this item does not commence at all. See subsection 2(4) of this Act.

#### **6 Subsection 3(1)**

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Insert:

***EC/EFTA attestation of conformity*** means an attestation of conformity (within the meaning of the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement) issued by an EC/EFTA conformity assessment body that is approved by the Secretary in writing.

### **7 Subsection 3(1)**

Insert:

***EC/EFTA conformity assessment body*** means a Conformity Assessment Body designated in one of the following Sectoral Annexes to the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement:

- (a) Sectoral Annex (Medical Devices);
- (b) Sectoral Annex (Medicinal Products GMP Inspection and Batch Certification).

### **8 Subsection 3(1)**

Insert:

***international instrument*** means:

- (a) any treaty, convention, protocol, agreement or other instrument that is binding in international law; and
- (b) a part of such a treaty, convention, protocol, agreement or other instrument.

### **9 Subsection 3(1)**

Insert:

***non-EC/EFTA attestation of conformity***, for a non-EC/EFTA MRA, means an attestation of conformity issued, after the non-EC/EFTA MRA has come into force, by a conformity assessment body that is designated in the non-EC/EFTA MRA and approved by the Secretary in writing for the non-EC/EFTA MRA.

### **10 Subsection 3(1)**

Insert:

***non-EC/EFTA MRA*** means an international instrument that Australia is bound by, or is a party to, if:

- (a) a purpose of the instrument is the recognition of attestations of conformity; and
  - (b) the instrument satisfies the requirements (if any) set out in regulations made for the purposes of this paragraph;
- but does not include:
- (c) the EC Mutual Recognition Agreement; or
  - (d) the EFTA Mutual Recognition Agreement.

### **11 After section 3A**

Insert:

### **3B Declaration—country covered by non-EC/EFTA MRA**

- (1) The Minister may declare, in writing, that a country specified in the declaration is covered by the non-EC/EFTA MRA specified in the declaration.
- (2) A declaration under subsection (1) must be published in the *Gazette*.

### **12 At the end of section 24D**

Add:

- (6) Despite subsection (5), if:
  - (a) the Secretary has given the applicant all evaluation reports relating to the application; and
  - (b) the Secretary has given those reports, or proposes to give those reports, to a committee established under the regulations to advise the Secretary on applications to register therapeutic goods to which subsection (1) applies; and
  - (c) the applicant withdraws the application after being given the reports, and before the end of the period mentioned in subsection (1);the evaluation is taken for the purposes of subsections (2), (3) and (4) to be completed immediately before the time of withdrawal.

### **13 Subparagraph 25(2)(a)(i)**

Repeal the subparagraph, substitute:

- (i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a

country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the goods; or

- (ia) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

#### **14 Paragraph 25B(1)(b)**

Omit “a conformity assessment certificate”, substitute “an EC/EFTA attestation of conformity”.

Note: The heading to section 25B is altered by omitting “**conformity assessment certificate**” and substituting “**EC/EFTA attestation of conformity**”.

#### **15 Subparagraph 26(2)(a)(i)**

Repeal the subparagraph, substitute:

- (i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the goods; or
- (ia) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

#### **16 Paragraph 26AA(1)(b)**

Omit “a conformity assessment certificate”, substitute “an EC/EFTA attestation of conformity”.

Note: The heading to section 26AA is altered by omitting “**conformity assessment certificate**” and substituting “**EC/EFTA attestation of conformity**”.

#### **17 Subparagraph 26A(4)(a)(i)**

Repeal the subparagraph, substitute:

- (i) if a step in the manufacture of the medicine has been carried out in a country that is a member of the

European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the medicine; or

- (ia) if a step in the manufacture of the medicine has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the medicine; or

## 18 After paragraph 37(1)(d)

Insert:

- (da) if the applicant proposes to carry out steps in the manufacture of blood or blood components under the licence—contain information relating to those steps set out in regulations made for the purposes of this paragraph; and

## 19 After paragraph 40(4)(a)

Insert:

- (aa) if:
  - (i) the holder of the licence carries out, or proposes to carry out, steps in the manufacture of blood or blood components under the licence; and
  - (ii) regulations made for the purposes of this paragraph set out particular information relating to those steps; comply with a request by the Secretary to provide such information, in accordance with those regulations; and

## 20 Application

- (1) The amendment made by item 12 applies in relation to applications made on or after the commencement of that item.
- (2) The amendment made by item 18 applies in relation to applications for licences made on or after the commencement of that item.
- (3) Paragraph 40(4)(a) of the *Therapeutic Goods Act 1989* as amended by this Schedule applies in relation to a request made under that paragraph on or after the commencement of this item, even if the licence to which the request relates was granted before that commencement.

## 21 Transitional

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- (1) An approval of a body as an approved conformity assessment body that was in force under the *Therapeutic Goods Act 1989* immediately before the commencement time has effect after the commencement time as if it were an approval of the body by the Secretary in writing for the purposes of the definition of ***EC/EFTA attestation of conformity*** in subsection 3(1) of the *Therapeutic Goods Act 1989* as in force after the commencement time.
- (2) In subitem (1):  
***commencement time*** means the time at which this item commences.

### ***Therapeutic Goods Amendment (Medical Devices) Act 2002***

#### **22 Item 7 of Schedule 1**

Repeal the item.

Note: If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences before section 2 of this Act, item 22 of this Schedule does not commence at all. See subsection 2(3) of this Act.

## Schedule 4—Therapeutic goods (listing conditions)

### *Therapeutic Goods Act 1989*

#### **1 Subsection 9A(5)**

Repeal the subsection, substitute:

- (5) The Minister may, by notice published in the *Gazette*:
  - (a) require that specified therapeutic goods be included in the part of the Register for listed goods; and
  - (b) specify the conditions subject to which such goods may be included in that part of the Register.

#### **2 Subsection 17(5)**

Repeal the subsection, substitute:

- (5) The Minister may, by notice published in the *Gazette*:
  - (a) require that specified therapeutic goods be included in the part of the Register for listed goods; and
  - (b) specify the conditions subject to which such goods may be included in that part of the Register.

Note: If Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002* commences before section 2 of this Act, this item does not commence at all. See subsection 2(5) of this Act.

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[Minister's second reading speech made in—  
House of Representatives on 21 March 2002]  
Senate on 20 June 2002

(90/02)

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