



Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017

made under subsection 10(1) of the

Therapeutic Goods Act 1989

Compilation No. 2

Compilation date: 28 March 2022

Includes amendments up to: F2022L00384

Prepared by the Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* that shows the text of the law as amended and in force on 28 March 2022 (the *compilation date*).

The notes at the end of this compilation (*the endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name of order

This order is the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.

3 Authority

This order is made under subsection 10(1) of the *Therapeutic Goods Act 1989*.

4 Interpretation

Note: A number of expressions used in this order are defined in subsection 3(1) of the Act, including the following:

- (a) batch;
- (b) British Pharmacopoeia;
- (c) container;
- (d) European Pharmacopoeia;
- (e) export only medicine;
- (f) label;
- (g) manufacture;
- (h) Register;
- (i) sponsor;
- (j) standard;
- (k) therapeutic goods;
- (l) United States Pharmacopoeia–National Formulary.

(1) In this order:

acceptance criteria, in relation to microbiological quality, are interpreted as:

- (a) 10^1 CFU: maximum acceptable count is 20;
- (b) 10^2 CFU: maximum acceptable count is 200;
- (c) 10^3 CFU: maximum acceptable count is 2000, and so forth.

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

batch number means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of a medicinal cannabis product, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution.

batch number prefix means the prefix which precedes the batch number and has the following characteristics:

- (a) clearly indicates that the information following the prefix is the batch number; and
- (b) is in the following form: ‘BATCH NUMBER’, ‘BATCH NO.’, ‘BATCH’, ‘B’, ‘(B)’, ‘B/N’, ‘LOT NUMBER’, ‘LOT NO.’, or

‘LOT’, or words or symbols to this effect, including a mixture of lower and upper case letters.

cannabis plant means any plant, or part of a plant, of the genus *Cannabis*, including, but not limited to, the flowers, fruiting tops, seeds, stems and leaves of the plant.

Note: Subspecies of the cannabis plant, *Cannabis sativa*, include *Cannabis sativa subsp. sativa*, *Cannabis sativa subsp. ruderalis* and *Cannabis sativa subsp. indica*.

EU Member State means a member state of the European Union.

EU Directive 2001/83/EC means *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, as in force or existing from time to time.

EU Directive 2003/94/EC means *Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*, as in force or existing at 28 March 2022.

excipient, for a medicinal cannabis product, means an ingredient that is not an active ingredient.

expiry date has the same meaning as in the Regulations.

expiry date prefix means a prefix which precedes the expiry date and has the following characteristics:

- (a) clearly indicates that the information following the prefix is the expiry date;
- (b) is in the following form: 'EXPIRY DATE', 'EXPIRY', 'EXPIRES', 'EXP. DATE', 'EXP', 'Use by' or 'Use before' or words to this effect, including a mixture of lower and upper case letters;
- (c) is not in the following form: 'Best by' or 'Best before' or words to this effect.

licensing authority means a body empowered to issue a certificate or other document to the effect that the body is satisfied that a manufacturing site complies with requirements for good manufacturing practice of therapeutic goods.

medicinal cannabis products means therapeutic goods that contain, or are manufactured from, any part of the cannabis plant.

PIC/S means the Pharmaceutical Inspection Co-operation Scheme established in 1995 as an extension to the Pharmaceutical Inspection Convention.

PIC/S Guide to GMP means the document *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021) published by PIC/S, as in force or existing from time to time, and includes the Annexes to that document other than the following:

- (a) Annex 4 (Manufacture of veterinary medicinal products other than immunologicals);
- (b) Annex 5 (Manufacture of immunological veterinary medical products);
- (c) Annex 14 (Manufacture of medicinal products derived from human blood or plasma).

plant material means dried or fresh material of the cannabis plant that has not undergone any refinement, including dried flos.

Note: Refinement does not include cutting or grinding material of the cannabis plant.

plant preparation means material of the cannabis plant that has undergone some refinement, excluding material of the cannabis plant that has been refined to a single cannabinoid.

Note: Refinement does not include cutting or grinding material of the cannabis plant.

processing aid means a substance used in the manufacture of a medicinal cannabis product that is not intended to remain in the final formulation of the product (although trace amounts may remain in the product).

quantity of the medicinal cannabis product means:

- (a) where the medicinal cannabis product consists of discrete dosage units, such as tablets or capsules or sachets—the stated number of units in the container;
- (b) where the medicinal cannabis product is:
 - (i) a solid or semi-solid—the stated weight in the container;
 - (ii) a liquid—the stated volume of fill in the container;
 - (iii) a pressurised metered-dose preparation or dry powder inhaler—the stated number of deliverable doses in the container;
 - (iv) a non-pressurised metered dose preparation—the minimum number of deliverable doses in the container;
- (c) where the medicinal cannabis product is a product of any of the kinds referred to in paragraph (b) and the product consists of a number of identical containers within the primary pack—the number of containers (for example, 5 x 10 mL vials);
- (d) for each of the individual containers within the primary pack, the quantity of the medicinal cannabis product to be included on the

individual container label would be as described in paragraph (b) (for example, the stated volume of fill in the container).

Regulations means the *Therapeutic Goods Regulations 1990*.

South African Guide to GMP means the document *4.01 - South African Guide to GMP* (July 2019, V7), published by the South African Health Products Regulatory Authority, as in force or existing from time to time.

stated content, in relation to each active ingredient in a medicinal cannabis product, means the quantity or proportion of each active ingredient that is:

- (a) specified on the label to be present in the medicinal cannabis product in accordance with any decision made by the Secretary under section 25 of the Act in relation to that product; or
- (b) disclosed to the Secretary in an application under section 19 of the Act for an approval or authority in relation to the medicinal cannabis product; or
- (c) disclosed to the Secretary in a notification under regulation 12A of the Regulations; or
- (d) purported to be present in a medicinal cannabis product that is extemporaneously compounded or repackaged by a pharmacist for a particular patient; or
- (e) notified to be present in a medicinal cannabis product for the purposes of item 3 of Schedule 5A to the Regulations.

TGO 95 means the *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95).

Therapeutic Goods Administration has the same meaning as in the Regulations.

- (2) Without limiting the meaning of **active ingredient** in subsection (1), the following substances are taken to be active ingredients for the purposes of this order (whether or not those ingredients are specified, disclosed, purported or notified to the Secretary to be active ingredients):
 - (a) any tetrahydrocannabinol present in a medicinal cannabis product, the quantity or proportion of which (together with any corresponding acid) is greater than or equal to 1.0% w/w or w/v of the product; and
 - (b) any other cannabinoid present in a medicinal cannabis product, the quantity or proportion of which (together with any corresponding acid) is greater than or equal to 2.0% w/w or w/v of the product.

5 Standard

This order constitutes a standard for medicinal cannabis products.

6 Application

- (1) Subject to subsection (2), this order applies to:
 - (a) medicinal cannabis products; and
 - (b) any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant.
- (2) This order does not apply to medicinal cannabis products that are:
 - (a) export only medicines; or
 - (b) mentioned in item 1 of Schedule 5 to the Regulations; or
 - (c) mentioned in items 4, 8, 10, 11 or 12 of Schedule 5A to the Regulations, subject to compliance with the conditions specified in those items.

7 Monograph

The standard constituted by the statements in the monograph titled *Pharmaceutical Preparations (2619)* in the European Pharmacopoeia applies with respect to:

- (a) medicinal cannabis products; and
- (b) any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant;

but does not apply to the extent of any inconsistency with this order.

Note: The *Pharmaceutical Preparations (2619)* monograph incorporates applicable requirements contained in other monographs that also need to be complied with, for example *Herbal Drugs (1433)*.

8 Active ingredients and cannabinoids

Each active ingredient and any other cannabinoid (that is not an active ingredient) in a medicinal cannabis product must comply with the following:

- (a) the active ingredient or other cannabinoid must be from the cannabis plant; and
- (b) the chemical structure of the active ingredient or other cannabinoid must not be modified or transformed in any way (including by chemical or other means).

Note: Modification or transformation does not include decarboxylation of naturally occurring acid forms of cannabinoids.

9 Decontamination

Any decontaminating treatment of the cannabis plant used in the manufacture of medicinal cannabis products must not:

- (a) adversely affect the quality of medicinal cannabis products; or
- (b) make use of, or otherwise contain, ethylene oxide.

10 Identification

The cannabis plants used in the manufacture of medicinal cannabis products must be positively identified using each of the following identification methods:

- (a) macroscopic examination; and
- (b) microscopic examination; and
- (c) chromatographic procedures.

11 Adulteration

- (1) Medicinal cannabis products and any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant, must not contain any substance that results in the adulteration of those products or ingredients.
- (2) For the purposes of subsection (1), adulteration includes the addition of, or substitution with, any substance that is extraneous to the formulation of the product, other than a processing aid.
- (3) In determining whether adulteration has occurred, it is irrelevant whether or not the addition or substitution is intended to improve, fortify or debase the medicinal cannabis product or any ingredients used in the manufacture of that product, including, but not limited to, the cannabis plant.

12 Tests

- (1) The tests mentioned in Schedule 1 are specified with respect to the cannabis plants used in the manufacture of medicinal cannabis products for the purposes of this order.
- (2) The following assay limits are specified for the purposes of this order:
 - (a) in relation to a medicinal cannabis product in herbal final form – the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 80.0 per cent and not more than 120.0 per cent of the stated content of that active ingredient; and

- (b) in relation to a medicinal cannabis product in tablet or capsule form, where that product is not included on the Register – the average content of each active ingredient, together with any corresponding acid, in a pooled sample of not fewer than 20 tablets or capsules must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content of that active ingredient; and
- (c) in relation to a medicinal cannabis product in any other dosage form – the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content of that active ingredient.

Note: The assay limits specified in the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* apply with respect to registered medicinal cannabis products in tablet or capsule form.

13 Manufacturing quality

- (1) This section does not apply to the manufacture of a medicinal cannabis product that is:
 - (a) plant material; or
 - (b) oil extracted directly from the cannabis plant;
used as starting material in the manufacture of another medicinal cannabis product.
- (2) Each step of manufacture in relation to a medicinal cannabis product that occurs outside Australia must be in accordance with one or more of the following:
 - (a) the PIC/S Guide to GMP;
 - (b) Article 47 of EU Directive 2003/94/EC;
 - (c) Article 47 of EU Directive 2001/83/EC;
 - (d) the South African Guide to GMP;
 - (e) *Part 211—Current Good Manufacturing Practice for Finished Pharmaceuticals of Subchapter C—Drugs: General*, in *Chapter I—Food and Drugs Administration of Title 21—Food and Drugs*, in the *United States Code of Federal Regulations*, as in force or existing from time to time;
 - (f) *Division 2 – Good Manufacturing Practices* in Part C of the *Food and Drug Regulations* (Canada), as in force or existing from time to time.
- (3) A medicinal cannabis product that is manufactured outside Australia must be manufactured at a site that is the subject of one or more of the following:

- (a) for a medicinal cannabis product manufactured in the United Kingdom—a valid certificate of good manufacturing practice issued to the manufacturer of the product by the Medicines and Healthcare products Regulatory Agency of the United Kingdom or a licensing authority of an EU Member State;
 - (b) for a medicinal cannabis product manufactured in an EU Member State—a valid certificate of good manufacturing practice issued to the manufacturer of the product by a licensing authority of an EU Member State;
 - (c) for a medicinal cannabis product manufactured in Canada—either:
 - (i) written confirmation from Health Canada that the manufacturing site operates in accordance with *Part 5: Good Production Practices of the Cannabis Regulations* SOR/2018-144 (Canada), as in force or existing from time to time, and:
 - (A) a valid certificate of good manufacturing practice issued to the manufacturer of the product by a licensing authority of an EU Member State; or
 - (B) written confirmation from the Therapeutic Goods Administration that the manufacturing site operates in accordance with the PIC/S Guide to GMP; or
 - (ii) a Drug Establishment Licence issued by Health Canada for the relevant medicinal cannabis product manufactured at the site;
 - (d) for a medicinal cannabis product manufactured in South Africa—written confirmation from the South African Health Products Regulatory Authority that the manufacturing site operates in accordance with the South African Guide to GMP;
 - (e) for a medicinal cannabis product manufactured in Israel—a valid certificate of good manufacturing practice issued to the manufacturer of the product by the Israel Ministry of Health;
 - (f) for a medicinal cannabis product manufactured in any other country—written confirmation from the Therapeutic Goods Administration that the manufacturing site operates in accordance with the PIC/S Guide to GMP.
- (4) A certificate or written confirmation mentioned in subsection (3) must:
- (a) cover the relevant medicinal cannabis product; and
 - (b) relate to each manufacturing site where the medicinal cannabis product was manufactured; and

- (c) have been current at the time the medicinal cannabis product was manufactured.

14 Child-resistant packaging

A medicinal cannabis product, other than a medicinal cannabis product in the form of plant material, must comply with the requirements specified in the following sections of TGO 95:

- (a) section 8 (general requirements); and
- (b) where the product is in a reclosable package—section 9 (reclosable packages); and
- (c) where the product is in a non-reclosable package—section 10 (non-reclosable packages).

15 Labels

- (1) A medicinal cannabis product must be labelled in accordance with this section.
- (2) The label of a medicinal cannabis product, other than a medicinal cannabis product that is extemporaneously compounded or repackaged by a pharmacist for a particular patient, must contain all the following information:
 - (a) the name of the medicinal cannabis product;
 - (b) the name and contact details of the sponsor of the medicinal cannabis product;
 - (c) the storage conditions applicable to the medicinal cannabis product;
 - (d) the batch number of the medicinal cannabis product preceded by the batch number prefix;
 - (e) the expiry date of the medicinal cannabis product preceded by the expiry date prefix;
 - (f) the name of each active ingredient of the medicinal cannabis product, and the quantity of each active ingredient (including appropriate units) stated as the anhydrous form;
 - (g) for each active ingredient of a medicinal cannabis product that is a plant preparation—all of the following:
 - (i) the weight of the plant preparation, and the minimum dry weight or fresh weight of the plant material from which it was prepared (including the word ‘minimum’), except where the plant preparation is an essential oil;
 - (ii) the plant species;
 - (iii) the plant part;

(iv) the preparation type;

Example: “*Cannabis sativa leaf dry extract 5 mg, derived from Cannabis sativa leaf dry 500 mg minimum, containing THC 30 mg*”.

(h) for each active ingredient of a medicinal cannabis product that is plant material—all of the following:

(i) the minimum dry weight or minimum fresh weight of plant material (including the word ‘minimum’);

(ii) the plant species;

(iii) the plant part;

Example: “*Cannabis sativa flower dry 500 mg minimum, containing THC 30 mg*”.

(i) the dosage form of the medicinal cannabis product;

(j) the quantity of the medicinal cannabis product.

(3) The label of a medicinal cannabis product that is extemporaneously compounded or repackaged by a pharmacist for a particular patient must state the name and quantity of each active ingredient that is purported to be present in the medicinal cannabis product.

(4) All of the information that is displayed on the label of a medicinal cannabis product must be:

(a) in English; and

(b) legible; and

(c) visible and not obscured; and

(d) durable.

16 Microbiological attributes

A medicinal cannabis product in oral dosage form must comply with the relevant acceptance criteria for microbiological quality of one of the following:

(a) the British Pharmacopoeia, Appendix XVI. D Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use, when tested by the methods of:

(i) the British Pharmacopoeia, Appendix XVI B. Microbiological Examination of Non-Sterile Products: 2. Microbial Enumeration Tests; and

(ii) the British Pharmacopoeia, Appendix XVI B. Microbiological Examination of Non-Sterile Products: 1. Test for Specified Micro-organisms; or

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- (b) the European Pharmacopoeia, Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use (5.1.4), when tested by the methods of:
 - (i) the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests (2.6.12); and
 - (ii) the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Test for Specified Micro-organisms (2.6.13); or
 - (c) the United States Pharmacopoeia–National Formulary, chapter <1111>, MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE, when tested by the methods of:
 - (i) the United States Pharmacopoeia–National Formulary, chapter <61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS; and
 - (ii) the United States Pharmacopoeia–National Formulary, chapter <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS; or
 - (d) the Special European Pharmacopoeia (Ph. Eur.) provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 1000 CFU per g or CFU per mL.

17 Application, savings and transitional provisions

Sections 13, 14, 15 and 16 apply to medicinal cannabis products released for supply in Australia on or after 1 July 2023.

Schedule 1 Specified tests

(subsection 12(1))

1 Interpretation

- (1) For each item specified in column 1 of this table, the parameter specified in column 2 must comply with the limits specified in column 4 under the test method from the European Pharmacopoeia specified in column 3.
- (2) With the exception of item 2 of this table, each limit specified in column 4 applies on a dried basis.

2 Table of specified tests

Specified tests			
Column 1 Item	Column 2 Parameter	Column 3 Test method	Column 4 Limits
1	Aflatoxins	Ph Eur 2.8.18	Not more than 2 µg/kg of aflatoxin B1 and not more than 4 µg/kg for the sum of aflatoxins B1, B2, G1, G2
2	Foreign matter	Ph Eur 2.8.2	Not more than 2.0%
3	Heavy metals	Ph Eur 2.4.8	Not more than 3.0 mg/kg of arsenic Not more than 0.5 mg/kg of cadmium Not more than 5.0 mg/kg of lead Not more than 0.5 mg/kg of mercury
4	Ochratoxin A	Ph Eur 2.8.22	Not more than 20 µg/kg
5	Pesticides	Ph Eur 2.8.13	Not more than the limits specified in Ph Eur 2.8.13
6	Total ash	Ph Eur 2.4.16	Not more than 20.0%

Note: In accordance with the European Pharmacopoeia, the unit mg/kg is the m/m measurement equivalent to ppm.

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
exp = expires/expired or ceases/ceased to have effect	renum = renumbered
F = Federal Register of Legislation	rep = repealed
gaz = gazette	rs = repealed and substituted
LA = <i>Legislation Act 2003</i>	s = section(s)/subsection(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sch = Schedule(s)
(md) = misdescribed amendment can be given effect	Sdiv = Subdivision(s)
(md not incorp) = misdescribed amendment cannot be given effect	SLI = Select Legislative Instrument
mod = modified/modification	SR = Statutory Rules
No. = Number(s)	Sub-Ch = Sub-Chapter(s)
	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
<i>Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)</i>	23 Mar 2017 (F2017L00286)	24 Mar 2017	—
<i>Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019</i>	28 Mar 2019 (F2019L00447)	31 Mar 2019	—
<i>Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022</i>	25 Mar 2022 (F2022L00384)	28 Mar 2022	—

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
s 1	am F2019L00447
s 2	rep LA s 48D
s 4	am F2019L00447; am F2022L00384
s 6	am F2022L00384
s 7	am F2022L00384
s 8	rs F2022L00384
s 11	am F2022L00384
s 12	am F2019L00447; am F2022L00384
s 13	ad F2022L00384
s 14	ad F2022L00384
s 15	ad F2022L00384
s 16	ad F2022L00384
s 17	ad F2022L00384
Sch 1	am F2022L00384
Note	rep F2022L00384
