

made under section 7AA of the

Therapeutic Goods Act 1989

Compilation No. 10

Compilation date: 1 July 2024

Includes amendments: F2024L00657; F2024L00692; F2024L00843

Prepared by the Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Excluded Goods) Determination 2018* that shows the text of the law as amended and in force on 1 July 2024 (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 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 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 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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

This instrument is the *Therapeutic Goods (Excluded Goods) Determination* 2018.

3 Authority

This instrument is made under section 7AA of the *Therapeutic Goods Act* 1989.

4 Definitions

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

- (a) advertise;
- (b) label;
- (c) medical device;
- (d) medicine;
- (e) Register;
- (f) supply;
- (g) therapeutic use.

In this instrument:

Act means the Therapeutic Goods Act 1989.

AS 2896–2011 means the document, Australian Standard: Medical gas systems – Installation and testing of non-flammable medical gas pipeline systems (AS 2896–2011), prepared by Committee HE-017 (Medical Gas Systems), approved on behalf of the Council of Standards Australia on 13 January 2011, and published by SAI Global Limited under licence from Standards Australia on 8 May 2011, as in force or existing immediately before the commencement of this instrument.

AS/NZS 2604:2021 means the document Australian/New Zealand Standard AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force or existing on 1 July 2024.

haematopoietic progenitor cells has the meaning given by clause 1 of Part 1 of Schedule 9 to the Regulations.

health professional has the same meaning as in the Medical Devices Regulations.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002.*

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Poisons Standard means the legislative instrument made under section 52D of the Act, as in force immediately before the commencement of this instrument.

Regulations means the Therapeutic Goods Regulations 1990.

secondary sunscreen product has the same meaning as in AS/NZS 2604:2021.

serious, for a condition, ailment or defect, has the same meaning as in the Medical Devices Regulations.

serious disease has the same meaning as in the Medical Devices Regulations.

5 Excluded goods

For subsection 7AA(1) of the Act, the goods specified in Schedule 1 are excluded goods for the purposes of the Act.

6 Excluded goods when used, advertised or presented for supply in a particular way

For subsection 7AA(2) of the Act, the goods specified in Schedule 2, when used, advertised, or presented for supply in a way specified in that Schedule are excluded goods for the purposes of the Act.

Schedule 1 Specified goods

(section 5)

Specified goods			
Column 1	Column 2		
Item	Specified goods		
1	adhesive removers and non-medicated skin cleansers relating to colostomy and ileostomy		
1A	anatomical models that are intended by the manufacturer to be used for educational or record-keeping purposes		
2	antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only		
2A	articles that are non-sterile personal protective equipment or safety apparel other than articles specified in item 1 of Schedule 1 to the <i>Therapeutic Goods (Medical Devices—</i> <i>Specified Articles) Instrument 2020</i>		
2B	cosmetic finishing components for orthoses and prostheses		
2C	craniofacial prostheses that are:		
	(a) spectacle-retained; or(b) adhesive-retained		
3	dental bleaches and dental whiteners		
3AA	dental impression trays		
3A	detergents and soaps for laundering or general cleaning use, other than detergents and soaps that are disinfectants within the meaning of the Regulations		
4	devices for measuring alcohol content in body fluids or exhaled air		
5	disinfectant and sterilant gases		
6	drinking water purification and treatment equipment		
7	ear candles		
7AA	ear moulds that are intended by the manufacturer to anchor hearing aids		
7A	fluoridated reticulated drinking water		
8	hair bleaches, hair dyes, hair-colorants and hair-perming preparations		
9	household and personal aids, or furniture and utensils, for people with disabilities		
10	incontinence pads, mattress overlays and mattress protectors		
10A	medicament trays that are intended by the manufacturer to hold medicaments		
11	menstrual pads other than tampons and menstrual cups		
11A	mouthguards intended by the manufacturer to be used to protect teeth from external forces including, but not limited to, mouthguards used in contact sports		
11B	ocular prostheses intended by the manufacturer to be used for cosmetic purposes		
11C	physical impressions of anatomy, and models cast from such impressions		

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Specified g	oods		
Column 1	Column 2		
Item	Specified goods		
12	sanitation, environmental control and environmental detoxification equipment (including films and coatings), other than articles specified in item 3 of Schedule 1 to the <i>Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020</i> Note: Sanitation, environmental control and environmental detoxification equipment		
12.4	does not include disinfectants within the meaning of the Regulations.		
12A	spectacle frames		
13	topical preparations applied to the nails to harden, or deter the biting of, nails		
14	 products containing sunscreen that are intended for application to the lips, and that: (a) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and (b) are a secondary sunscreen product; and (c) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and (d) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and (e) meet the performance requirements for a broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021 		
14A	software that is:		
	 (a) intended by its manufacturer to be used by a consumer for the self-management of an existing disease, condition, ailment or defect that is not a serious disease or serious condition, ailment or defect; and (b) not intended by its manufacturer to be used: (i) in clinical practice; or (ii) in relation to a serious disease or serious condition, ailment or defect; or (iii) for the purpose of diagnosis, treatment, or making a specific recommendation or decision about the treatment, of a disease, condition, ailment or defect that is not a serious disease or serious condition, ailment or defect 		
14B	software, or a combination of software and non-invasive hardware, that is:		
	 (a) intended by its manufacturer to be used by a consumer to promote or facilitate general health or wellness by measuring or monitoring (through non-invasive means) a physical parameter, such as movement, sleep, heart rate, heart rhythm, temperature, blood pressure or oxygen saturation; and (b) not intended by its manufacturer to be used: (i) in clinical practice; or (ii) for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision 		
	about the treatment, of a serious disease or a serious condition, ailment or defect		
14C	software that is:		

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Specified g	oods			
Column 1	Column 2			
Item	Specified goods			
	 (a) intended by its manufacturer to be used by a consumer to improve general health or wellness by coaching, or encouraging behavioural change, in relation to personal or environmental factors, such as weight, exercise, sun exposure or dietary intake; and (b) not intended by its manufacturer to be used: (i) in clinical practice or to provide information to the consumer that would generally be accepted to require the interpretation of a health professional; or (ii) for the purpose of diagnosis, prognosis, or making a decision about the treatment, of a disease, condition, ailment or defect 			
14D	software that is:			
	 (a) intended by its manufacturer to be used as a patient reported outcome measures (PROMs) questionnaire or patient survey; and (b) not intended by its manufacturer to diagnose, screen for, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect 			
14E	software that is a digital mental health tool (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user			
14F	software that is:			
	 (a) intended by its manufacturer to enable communications, including the transmission of patient information, for the purposes of supporting the delivery of health services; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect 			
14G	software that is:			
	 (a) intended by its manufacturer to be used for the administration or management of health processes or facilities (including financial records, claims, billing, appointments, operating theatre management, hospital bed management, schedules, business analytics, admissions, inventory and workflow); and (b) not intended by its manufacturer to be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a disease, condition, ailment or defect 			
14H	software that is intended by its manufacturer to be used for the sole purpose of storing or transmitting patient images			
14I	software that is:			
	(a) intended by its manufacturer to be used for the sole purpose of providing alerts to health professionals in relation to patient care; and			

Specified g	bods			
Column 1	Column 2			
Item	Specified goods			
	 (b) not intended by its manufacturer to: (i) replace the clinical judgement of a health professional; or (ii) diagnose, screen for, prevent, alleviate, treat, or make a decision about the treatment of, a disease, condition, ailment or defect 			
14J	software that is:			
	 (a) intended by its manufacturer to be used for clinical workflow management; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect 			
14K	software that is middleware and is:			
	 (a) intended by its manufacturer to connect or interface applications to an underlying operating system or another application, including by communicating or transmitting information; and (b) not intended by its manufacturer to: 			
	(i) control medical devices; or(ii) perform analysis, computation or logic that relates to the intended purpose			
	 (ii) perform analysis, computation of logic that relates to the intended purpose of a medical device; or (iii) be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a disease, condition, ailment or defect 			
14L	software that is a calculator and:			
	 (a) either: (i) uses relevant published clinical standards or authoritative sources to make calculations; or (ii) displays calculations and outputs in a manner that may be validated by the user; and 			
	(b) is not intended by its manufacturer to control the administration of a calculated dosage			
14M	software, or a combination of software and hardware, that is an electronic health record (however named or described) and is:			
	 (a) intended by its manufacturer to be used in clinical practice by healthcare providers to collect, use, disclose and otherwise manage patient clinical data within or between healthcare facilities; and 			
	(b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect			
14N	software that is data analytics and is:			
	(a) intended by its manufacturer to be used for the collection and analysis of class, group or population data; and			

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Specified goods			
Column 1	Column 2 Specified goods		
Item			
	(b) not intended by its manufacturer to be used for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation, of a disease, condition, ailment or defect in relation to individuals		
140	software that is a laboratory information management system (however named or described) and is not intended by its manufacturer to:		
	 (a) manipulate information or data to change, or generate new, diagnostic outputs (other than automating simple calculations or generating report comments); or (b) prevent, monitor, predict, make a prognosis of, treat or alleviate a disease, condition, ailment or defect 		
15	tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen and that:		
	 (a) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and 		
	(b) are a secondary sunscreen product; and		
	(c) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and		
	(d) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and		
	(e) meet the performance requirements for a broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021		

Schedule 2 Specified goods used, advertised or presented for supply in a particular way

(section 6)

Specified goods			
Column 1	Column 2	Column 3	
Item	Specified goods	When used, advertised or presented for supply in a particular way	
1	anti-acne skin care products, including spot treatments, cleansers, face scrubs and masks, that do not contain any substance included in Schedules 2, 3, 4 or 8 to Poisons Standard	when advertised or presented for supply as controlling or preventing acne only through cleansing, moisturising, exfoliating or drying the skin	
2	antibacterial skin care products that do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard	 when advertised or presented for supply as being active against bacteria and not advertised or presented for supply as being: (a) active against viruses, fungi or other microbial organisms (other than bacteria); or (b) for use in connection with disease, disorders or medical conditions; or (c) active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or (d) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or (e) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or (f) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or (g) for use in connection with a procedure involving venepuncture or delivery of an injection 	

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3	anti-dandruff hair care products	when advertised or presented for supply as controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp	
4	compressed gases	when used as a power source for medical devices	
4A	 goods in relation to which the following paragraphs apply: (a) the goods comprise, contain or are derived from, human cells or human tissues collected from a patient (the <i>relevant patient</i>) who is under the clinical care of a medical or dental practitioner (the <i>relevant practitioner</i>); (b) the relevant practitioner is registered in a State or internal Territory; (c) subject to paragraph (d), all steps in the manufacture of the goods are carried out by, or under the professional supervision of, the relevant practitioner in a hospital in a State or internal Territory (the <i>relevant hospital</i>); (d) if a step in the manufacture of the goods relating to the storage or testing of the goods is not carried out in the relevant hospital, it is carried out by a person under contract with the relevant hospital 	 when the goods are: (a) used for the relevant patient, who is a patient of the relevant hospital; and (b) not advertised directly to consumers 	
4B	goods that are fresh viable human haematopoietic progenitor cells	when used for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution	
4C	goods that are fresh viable human organs or parts of human organs	when used for direct donor-to-host transplantation	
4D	goods that are human reproductive tissue	when used in assisted reproductive therapy	
4E	goods that are: (a) human eggs; or	when used in carrying out an activity as authorised or purportedly authorised by a mitochondrial	

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	(b) human sperm	donation licence under the Research Involving Human Embryos Act 2002
5	moisturising skin care products	when the product:
	containing sunscreen that are intended for dermal application (including anti- wrinkle, anti-ageing and skin whitening	 (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and
	 products), and that: (a) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and (b) are a secondary sunscreen product; and (c) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and (d) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604: 	 (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months—includes an expiry date on its label; and (d) has a pack size not larger than 300 mL or 300 g; and (e) does not have any therapeutic claims made in relation to it (including claims about skin cancer), other than those in relation to premature ageing in connection with sun exposure
	 2021; and (e) meet the performance requirements for a broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021 	
6	oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 to Poisons Standard	 when advertised or presented for supply, the following two paragraphs apply: (a) the only benefits claimed to result from the use of the product is consequential on improvements to oral hygiene, including for the prevention of tooth decay or the us of fluoride for the prevention of tooth decay; and (b) benefits in relation to such other diseases or aliments, such as gum or other oral disease or periodontal condition, are not claimed to result

7	packs and kits containing medical	when advertised or presented for supply	
	devices for the prevention of blood borne and sexually transmissible diseases where each individual therapeutic good contained within the packs or kits is already included on the Register	as a part of a Government endorsed health promotion program, having been expressly authorised by that Government as part of that program	
8	piped medical gas systems	when installed and used in compliance with AS 2896–2011	
9	preparations containing a sunscreening substance, if the primary purpose of the preparation is neither protection from solar radiation nor another therapeutic purpose	 when the preparation is not advertised or presented for supply with: (a) a statement of claimed sun protection factor; or (b) a description of a claimed sun protection factor; or (c) a reference to another therapeutic 	
10	sunbathing skin care products that	use in respect of the preparation when the product:	
	contain sunscreen (such as oils, creams, gels, tanning products without sun, and after-sun care products), and that:	 (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and 	
	 (a) have a sun protection factor of at least 4 and not more than 15; and (b) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and 	 (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months—includes an expiry date on its label; and (d) has a pack size not larger than 300 mL or 300 g; and 	
	 (c) are a secondary sunscreen product; and (d) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of 	 (e) does not have any therapeutic claims made in relation to it (including claims about skin cancer), other than those in relation to premature ageing in connection with sun exposure 	
	AS/NZS 2604:2021; and (e) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and		
	(f) meet the performance requirements for a		

	broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS	
11	2604:2021 therapeutic goods for retaining, cushioning or repairing dentures	when advertised or presented for supply to the ultimate consumer

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 how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

Endnote 2—Abbreviation key

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

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Excluded Goods) Determination 2018	27 Sep 2018 (F2018L01350)	1 Oct 2018	_
Therapeutic Goods Amendment (Excluded Goods) Determination 2019	21 June 2019 (F2019L00853)	22 June 2019	_
Therapeutic Goods Amendment (Excluded Goods) Determination (No. 2) 2019	15 July 2019 (F2019L00985)	16 July 2019	_
Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020	23 Apr 2020 (F2020L00464)	24 Apr 2020	_
Therapeutic Goods (Excluded Goods) Amendment (Software- based Products) Determination 2021	15 Jan 2021 (F2021L00047)	25 Feb 2021	_
Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021	11 Feb 2021 (F2021L00112)	12 Feb 2021	_
Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021	30 Jul 2021 (F2021L01049)	31 Jul 2021	
Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021	20 Aug 2021 (F2021L01161)	21 Aug 2021	_
Mitochondrial Donation Law Reform (Maeve's Law) Act 2022	5 Apr 2022 (C2022A00026)	Sch 1 (item 116); 1 Oct 2022 (s 2(1) item 2)	—
Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023	15 Dec 2023 (F2023L01684)	1 Jan 2024	_
Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024	7 Jun 2024 (F2024L00657)	1 Jul 2024	_
Therapeutic Goods (Excluded Goods) Amendment Determination 2024	17 Jun 2024 (F2024L00692)	1 Jul 2024	_
Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024	30 Jun 2024 (F2024L00843)	1 Jul 2024	_

Endnote 3—Legislation history

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Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
s 2	rep LA s 48D
s 3	am F2019L00853
s 4	am F2019L00853; F2021L00047; F2021L00112; F2021L01161; F2024L00657
s 7	ad F2023L01684;
	am F2024L00657; F2024L00692
	rep F2024L00843
Schedule 1	am F2019L00985; F2020L00464; F2021L00047; F2021L00112; F2021L01049; F2021L01161; F2023L01684; F2024L00657
Schedule 2	am F2019L00853; C2022A00026; F2024L00657
Note	rep F2019L00853