EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2022 (No. 11)

PB 99 of 2022

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to make changes to the pharmaceutical benefits listed for the purposes of the Pharmaceutical Benefits Scheme (PBS), and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)), participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Paragraph 88(1EB) provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit allowing the benefit to be supplied only.

This legislative instrument is made pursuant to section 88 and subsection 100(2) of the *National Health Act 1953* (the Act).

Supplying pharmaceutical benefits

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

Paragraph 85(7A) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under one or more of the prescriber bag provisions.

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

Variation and revocation

Unless there is an express power to revoke or vary PB 71 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 71 of 2012.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the PBAC is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

Changes to PB 71 of 2012 made by this Instrument

Schedule 1 to this Instrument provides for the addition of the listed drugs burosumab, cemiplimab, and tepotinib and forms of the listed drugs phenelzine, and pyridostigmine to the PBS Schedule. It also provides for: the deletion of forms of the listed drugs abacavir with lamivudine, and triglycerides - medium chain, formula; and the alteration of circumstances in which a prescription may be written for the supply of the listed drugs abemaciclib, aflibercept, atezolizumab, brolucizumab, clopidogrel, dexamethasone, lacosamide, molnupiravir, nintedanib, nirmatrelvir and ritonavir, nivolumab, pembrolizumab, pirfenidone, ranibizumab, somatropin, triptorelin, and ustekinumab.

Schedule 1 to this Instrument also provides for the following changes:

- the addition of 13 brands of existing pharmaceutical items;
- the deletion of 23 brands of existing pharmaceutical items;
- the addition of a pack quantity for 2 existing pharmaceutical items;
- the alteration of responsible persons code for 10 existing brand of pharmaceutical item;
- the addition of 1 responsible person to the list of responsible persons;
- the addition of 2 existing pharmaceutical items covered under supply only arrangements; and
- the deletion of 9 pharmaceutical items covered under Supply Only arrangements.

These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

General

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 November 2022.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2022 (No. 11)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 11)* and may also be cited as PB 99 of 2022.

Section 2 Commencement

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, Schedule 1 to the Instrument commences on 1 November 2022.

Section 3 Authority

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the addition of new pack quantities, the alteration of responsible person code for brands of pharmaceutical benefits, the addition of a responsible person to the list of responsible persons, the addition and deletion of benefits covered under Supply Only arrangements, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme. These changes are summarised below.

SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME MADE BY SCHEDULE 1 OF THIS INSTRUMENT

Drugs Added

Listed Drug

Burosumab

Cemiplimab

Tepotinib

Forms Added

Listed Drug	***Form***
Phenelzine	Tablet 15 mg (as sulfate) s19A
Pyridostigmine	Tablet containing pyridostigmine bromide 180 mg (modified release) s19A

Forms Deleted

Listed Drug	*Form*
Abacavir with lamivudine	Tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg
Triglycerides - medium chain, formula	Oral liquid 500 mL, 8 (Nutrini Peptisorb)

Brands Added

Listed Drug	*Form and Brand*
Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL *(Bevaciptin)*
	Solution for I.V. infusion 400 mg in 16 mL *(Bevaciptin)*
Bortezomib	Powder for injection 3.5 mg *(Bortezomib Baxter)*
Dasatinib	Tablet 20 mg *(Dasatinib SUN)*
	Tablet 50 mg *(Dasatinib SUN)*
	Tablet 70 mg *(Dasatinib SUN)*
	Tablet 100 mg *(Dasatinib SUN)*
Rabeprazole	Tablet containing rabeprazole sodium 20 mg (enteric coated) *(Noumed Rabeprazole)*
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride *(Sitagliptin/Metformin Sandoz)*
	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride *(Sitagliptin/Metformin Sandoz)*
	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride *(Sitagliptin/Metformin Sandoz)*
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride) *(Vancomycin Viatris)*
	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride) *(Vancomycin Viatris)*

Brands Deleted

Listed Drug	*Form and Brand*
Amoxicillin	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL *(Alphamox 125)*
	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL *(Alphamox 250)*
Candesartan	Tablet containing candesartan cilexetil 32 mg *(Candesartan GH)*
Famciclovir	Tablet 125 mg *(Ezovir)*

	Tablet 250 mg *(Ezovir; Famciclovir generichealth 250)*
	Tablet 500 mg *(Famciclovir generichealth 500)*
Flucloxacillin	Powder for injection 1 g (as sodium monohydrate) *(Flubiclox)*
Metformin	Tablet (extended release) containing metformin hydrochloride 1 g *(METEX XR 1000)*
Piroxicam	Capsule 10 mg *(Mobilis 10)*
	Capsule 20 mg *(Mobilis 20)*
	Dispersible tablet 20 mg *(Mobilis D-20)*
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms *(Pramipexole XR GP)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms *(Pramipexole XR GP)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg *(Pramipexole XR GP)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg *(Pramipexole XR GP)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg *(Pramipexole XR GP)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg *(Pramipexole XR GP)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg *(Pramipexole XR GP)*
Roxithromycin	Tablet 300 mg *(Rulide)*
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 *(Asmol 2.5 uni-dose)*
	Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 *(Asmol 5 uni-dose)*
Tacrolimus	Capsule 5 mg *(Pacrolim)*

Addition of Pack Quantity

Listed Drug	Form	Brand Name	Pack Quantity
Pomalidomide	Capsule 3 mg	*Pomalidomide Sandoz*	14
	Capsule 4 mg	*Pomalidomide Sandoz*	14

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	*DuoResp Spiromax*	***From:*** AF ***To:*** EV
	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2	*DuoResp Spiromax*	***From:*** AF ***To:*** EV
Imatinib	Tablet 100 mg (as mesilate)	*Imatinib-Teva*	***From:*** SZ ***To:*** TB
	Tablet 400 mg (as mesilate)	*Imatinib-Teva*	***From:*** SZ ***To:*** TB
Quetiapine	Tablet (modified release) 50 mg (as fumarate)	*Tevatiapine XR*	***From:*** SZ ***To:*** TB
	Tablet (modified release) 150 mg (as fumarate)	*Tevatiapine XR*	***From:*** SZ ***To:*** TB
	Tablet (modified release) 200 mg (as fumarate)	*Tevatiapine XR*	***From:*** SZ ***To:*** TB
	Tablet (modified release) 300 mg (as fumarate)	*Tevatiapine XR*	***From:*** SZ ***To:*** TB
	Tablet (modified release) 400 mg (as fumarate)	*Tevatiapine XR*	***From:*** SZ ***To:*** TB
Tiotropium	Capsule containing powder for oral inhalation 13 micrograms (as bromide) (for use in Zonda device)	*Braltus*	***From:*** AF ***To:*** TB

Addition of Responsible Person Code

KYOWA KIRIN AUSTRALIA PTY LTD *(KO)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Abemaciclib

Aflibercept

Atezolizumab

Brolucizumab

Clopidogrel

Dexamethasone

Lacosamide

Molnupiravir

Nintedanib

Nirmatrelvir and ritonavir

Nivolumab

Pembrolizumab

Pirfenidone

Ranibizumab

Somatropin

Triptorelin

Ustekinumab

Supply Only – Additions

Note: *Supply Only benefits are available on the Schedule for dispensing only, for a period of up to 12 months.*

Listed Drug	*Form and Brand*
Phenelzine	Tablet 15 mg (as sulfate) (USP) *(Phenelzine sulfate USP (Generic Health))*
Triglycerides, medium chain	Oral liquid 225 mL, 15 (betaquik) *(Betaquik)*

Supply Only – Deletions

Listed Drug	*Form and Brand*
Clopidogrel	Tablet 75 mg (as besilate) *(BTC Clopidogrel; Clopidogrel GH; Clovix 75; Plidogrel)*
	Tablet 75 mg (as hydrogen sulfate) *(Blooms the Chemist Clopidogrel; Clopidogrel Sandoz Pharma; Clopidogrel Winthrop; Iscover; Piax)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Molnupiravir Nirmatrelvir and ritonavir	**Modified Monash Model (MMM).** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The MMM is used to define whether a location where a person lives is a city, rural, remote or very remote.	The MMM is available for download for free from the Department of Health website: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm
Somatropin	**The Centers for Disease Control and Prevention (US) Clinical Growth Charts 2000** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. Growth charts (length-for-age and stature-for-age) consist of a series of percentile curves that illustrate the distribution of length/height in children. They are used to track the growth of infants, children, and adolescents. These are tools that contribute to forming an overall clinical impression for the child being measured.	The relevant CDC Clinical Growth Charts (length-for-age and stature-for-age) can be viewed, printed and reproduced via Adobe Acrobat for free from the U.S Department of Health & Human Services website: https://www.cdc.gov/growthcharts/clinical_charts.htm
Atezolizumab Cemiplimab Nivolumab Pembrolizumab Tepotinib	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/ Performance Status Score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.).	The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-performance-status

Diagnostic tools referenced in the Instrument

The following standard medical diagnostic tools are referenced in the Instrument but are not intended to incorporate a document by reference.

Listed Drug	***Diagnostic tool***	***Purpose and use in the Instrument***	***Reason this reference does not serve to incorporate a document***
Aflibercept Dexamethasone Ranibizumab	**Early treatment diabetic retinopathy study chart (ETDRSC) and Snellen chart**	The ETDRSC and Snellen chart are eye charts that are routinely used in clinical practice to measure visual acuity. Measurement results must be reported on as part of the authority application for a number of PBS listed drugs.	Measurement of visual acuity using the ETDRSC and/or Snellen chart is a process for obtaining physiological measurements and does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met. It is part of the standard diagnostic work-up for macular oedema.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 11)

(PB 99 of 2022)

This Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Instrument

The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 11)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

Human rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

The Instrument advances the right to health and the right to social security by providing new drugs, and new forms and brands of existing listed drugs, and ensuring the deletion of forms and brands of listed drugs does not affect access to PBS medicines. The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to

medicines on the PBS are evidence-based. The Instrument includes the addition of three new drugs, two new forms across two existing drugs and the addition of 13 new brands across 13 existing forms, which allows for greater patient access to these drugs.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Principal Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of drugs and forms of drugs in the abovementioned instruments, would not result in an unmet clinical need. The delisting of these items will not affect access to the drugs, as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2022, these fees are up to $42.50 for general patients and up to $6.80 for concession card holders.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

The drug abacavir with lamivudine (Abacavir/Lamivudine GH 600/300®) in the form tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg was requested to be delisted from the PBS by the sponsor. An alternative product remains listed on the PBS and accessible for patients.

The drug triglycerides - medium chain, formula (Nutrini Peptisorb®) in the form oral liquid 500 mL, 8 (Nutrini Peptisorb) was requested to be delisted from the PBS by the sponsor.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

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