EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2022 (No. 1)

PB 1 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 on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS 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 forms of the listed drugs levothyroxine, and upadacitinib to the Schedule of Pharmaceutical Benefits. It also provides for the deletion of forms of the listed drugs adrenaline (epinephrine), and ribavirin, and for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs acalabrutinib, dupilumab, ezetimibe, ibrutinib, and imatinib.

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

- the addition of 55 brands of existing pharmaceutical items;
- the deletion of 14 brands of existing pharmaceutical items;
- the alteration of a brand name for 1 existing pharmaceutical item;
- the addition of 1 maximum quantity for an existing pharmaceutical item;
- the addition of 2 responsible persons to the list of responsible persons;
- the alteration of responsible person codes for 4 existing brands of pharmaceutical items; and
- the deletion of 1 brand of existing pharmaceutical item from supply only.

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 February 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. 1)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 1)* and may also be cited as PB 1 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 February 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 and deletion of forms of listed drugs, the addition and deletion of brands, the alteration of a brand name, the addition of a maximum quantity and number of repeats, the addition of responsible persons to the list of responsible persons, the alteration of responsible person codes for brands of pharmaceutical benefits, the deletion of one brand of a pharmaceutical item from supply only status, 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

Forms Added

Listed Drug	*Form*
Levothyroxine	Tablet containing 125 micrograms anhydrous levothyroxine sodium
Upadacitinib	Tablet 30 mg

Forms Deleted

Listed Drug	*Form*
Adrenaline (epinephrine)	Solution for injection 1 mg (as tartrate) in 1 mL (1 in 1,000)
Ribavirin	Tablet 400 mg
	Tablet 600 mg

Brands Added

Listed Drug	*Form and Brand*
Bortezomib	Powder for injection 1 mg *(Bortezomib Accord)*
	Powder for injection 2.5 mg *(DBL Bortezomib)*

	Powder for injection 3 mg *(DBL Bortezomib)*
	Powder for injection 3.5 mg *(Bortezom; Bortezomib Accord; Bortezomib Sandoz; Bortezomib-Dr.Reddy's; BORTEZOMIB-TEVA; DBL Bortezomib)*
Dasatinib	Tablet 20 mg *(Dasatinib ARX; Dasatinib Dr.Reddy's)*
	Tablet 50 mg *(Dasatinib ARX; Dasatinib Dr.Reddy's)*
	Tablet 70 mg *(Dasatinib ARX; Dasatinib Dr.Reddy's)*
	Tablet 100 mg *(Dasatinib ARX; Dasatinib Dr.Reddy's)*
Dimethyl fumarate	Capsule (modified release) 120 mg *(Pharmacor Dimethyl Fumarate)*
	Capsule (modified release) 240 mg *(Pharmacor Dimethyl Fumarate)*
Escitalopram	Tablet 10 mg (as oxalate) *(NOUMED ESCITALOPRAM)*
	Tablet 20 mg (as oxalate) *(NOUMED ESCITALOPRAM)*
Ezetimibe with simvastatin	Tablet 10 mg-10 mg *(EZEVYT 10/10)*
	Tablet 10 mg-20 mg *(EZEVYT 10/20)*
	Tablet 10 mg-40 mg *(EZEVYT 10/40)*
	Tablet 10 mg-80 mg *(EZEVYT 10/80)*
Fludrocortisone	Tablet containing fludrocortisone acetate 100 micrograms *(FLUDROCORTISONE MEDSURGE)*
Fulvestrant	Injection 250 mg in 5 mL pre-filled syringe *(FULVESTRANT EVER PHARMA)*
Glatiramer	Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe *(Glatira; GLATIRAMER ACETATE-TEVA)*
Hypromellose	Eye drops 3 mg per mL, 10 mL *(Revive Tears)*
Levothyroxine	Tablet containing 50 micrograms anhydrous levothyroxine sodium *(Eltroxin; LEVOXINE)*
	Tablet containing 75 micrograms anhydrous levothyroxine sodium (*Eltroxin; LEVOXINE)*
	Tablet containing 100 micrograms anhydrous levothyroxine sodium (*Eltroxin; LEVOXINE)*
	Tablet containing 200 micrograms anhydrous levothyroxine sodium (*Eltroxin; LEVOXINE)*
Mefenamic acid	Capsule 250 mg *(FEMIN)*
Mesalazine	Tablet 1.2 g (prolonged release) *(Mesalazine 1.2 TAKEDA)*
Methylphenidate	Tablet containing methylphenidate hydrochloride 18 mg (extended release) *(METHYLPHENIDATE-TEVA XR)*
	Tablet containing methylphenidate hydrochloride 27 mg (extended release) *(METHYLPHENIDATE-TEVA XR)*
	Tablet containing methylphenidate hydrochloride 36 mg (extended release) *(METHYLPHENIDATE-TEVA XR)*
	Tablet containing methylphenidate hydrochloride 54 mg (extended release) *(METHYLPHENIDATE-TEVA XR)*

Mirtazapine	Tablet 30 mg *(NOUMED MIRTAZAPINE)*
	Tablet 45 mg *(NOUMED MIRTAZAPINE)*
Nitrofurantoin	Capsule 50 mg *(Nitrofurantoin BNM)*
	Capsule 100 mg *(Nitrofurantoin BNM)*
Oxycodone	Tablet containing oxycodone hydrochloride 5 mg *(Oxyndone)*
Telmisartan	Tablet 40 mg *(NOUMED TELMISARTAN)*
	Tablet 80 mg *(NOUMED TELMISARTAN)*
Topiramate	Tablet 25 mg *(NOUMED TOPIRAMATE)*
	Tablet 50 mg *(NOUMED TOPIRAMATE)*
	Tablet 100 mg *(NOUMED TOPIRAMATE)*
	Tablet 200 mg *(NOUMED TOPIRAMATE)*

Brands Deleted

Listed Drug	***Form and Brand***
Atazanavir	Capsule 200 mg (as sulfate) *(Atazanavir Mylan)*
	Capsule 300 mg (as sulfate) *(Atazanavir Mylan)*
Azacitidine	Powder for injection 100 mg *(Celazadine)*
Bosentan	Tablet 62.5 mg (as monohydrate) *(Bosentan Sandoz)*
	Tablet 125 mg (as monohydrate) *(Bosentan Sandoz)*
Clopidogrel	Tablet 75 mg (as hydrogen sulfate) *(Clopidogrel Sandoz)*
Insulin glargine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 *(Semglee)*
Isosorbide mononitrate	Tablet 60 mg (sustained release) *(Isomonit)*
Nifedipine	Tablet 30 mg (controlled release) *(Adefin XL 30)*
	Tablet 60 mg (controlled release) *(Adefin XL 60)*
Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe *(Fulphila)*
Piroxicam	Capsule 20 mg *(Feldene)*
Ranitidine	Tablet 150 mg (as hydrochloride) *(Rani 2)*
	Tablet 300 mg (as hydrochloride) *(Rani 2)*

Alteration of Brand Name

Listed Drug	***Form***	***Brand Name***	
Daratumumab	Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL	***From:*** Darzalex	***To:*** Darzalex SC

Addition of Maximum Quantity and Number of Repeats

Listed Drug	***Form***	***Brand Name***	***Maximum Quantity***	***Number of Repeats***
Upadacitinib	Tablet 15 mg	*Rinvoq*	28	4

Addition of Responsible Person Code

Pharmaco (Australia) Limited *(FJ)*

Aspen Pharmacare Australia Pty Limited *(LT)*

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*	
Disopyramide	Capsule 100 mg	*Rythmodan*	***From:*** SW	***To:*** PB
Doxorubicin - pegylated liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	*Caelyx*	***From:*** JC	***To:*** BX
	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 50 mg in 25 mL	*Caelyx*	***From:*** JC	***To:*** BX
Omeprazole	Tablet 20 mg (as magnesium)	*Acimax Tablets*	***From:*** AL	***To:*** FJ

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Acalabrutinib

Dupilumab

Ezetimibe

Ibrutinib

Imatinib

Supply Only - Deletion

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*
Exenatide	Injection (modified release) 2 mg single dose pre-filled pen *(Bydureon)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Dupilumab Upadacitinib	**Dermatology Life Quality Index (DLQI).** 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 DLQI is designed to measure the health-related quality of life of adult patients suffering from a skin disease.	The DLQI is available for download for free from the Cardiff University website: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
Dupilumab Upadacitinib	**Eczema Area and Severity Index (EASI).** 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 EASI is a validated scoring system that grades the physical signs of atopic dermatitis/eczema.	Instructions on the use of the Eczema Area and Severity Index and copyright details are available for download for free from the Dupixent (UK) website: https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf
Dupilumab Upadacitinib	**Physicians Global Assessment (PGA) (5-point scale).** 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 Physician's Global Assessment is not publicly available, but can be obtained free of charge from Sanofi Medical Information, along with

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	The PGA is a 5-point scale that measures the severity of atopic dermatitis.	instructions on the use of the Physician's Global Assessment (5-point scale) by phoning 1800 818 806 or email MedInfo.Australia@sanofi.com
Acalabrutinib Ibrutinib	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status.** 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

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. 1)

(PB 1 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. 1)* (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 forms and brands of listed drugs and ensuring the deletion of forms and brands of listed drugs do 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 two new forms of an existing drug and the addition of 55 new brands across 41 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. PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from 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 the form 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.

If 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 Ribavirin in the forms Tablet 400 mg and Tablet 600 mg was requested to be delisted from the PBS by the sponsor due to the discontinuation of the products. The PBAC considered this request at its meeting in March 2021 and advised that the delisting of this drug from the PBS would result in an unmet clinical need. On 1 December 2021, Ribavirin in the form Tablet 200 mg was listed on the PBS under the same conditions as the Tablet 400 mg and Tablet 600 mg forms and will remain listed on the PBS following the delisting of the Tablet 400 mg and Tablet 600 mg forms. The Tablet 200 mg form is expected to meet the clinical need for this drug previously identified by the PBAC.

Due to the shortage of the drug Adrenaline (epinephrine) in the form Solution for injection 1 mg (as tartrate) in 1 mL (1 in 1,000), temporary approval under section 19A of the *Therapeutic Goods Act 1989* was granted for the import and supply of a medicine that is not registered on the Australian Register of Therapeutic Goods. The shortage has been resolved and approval lapsed. Patient access has not been affected as the approved form of the drug is now available.

Conclusion

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

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