Minutes of the PHARMAC Prioritisation Meeting

10 December 2019

Meeting attendees

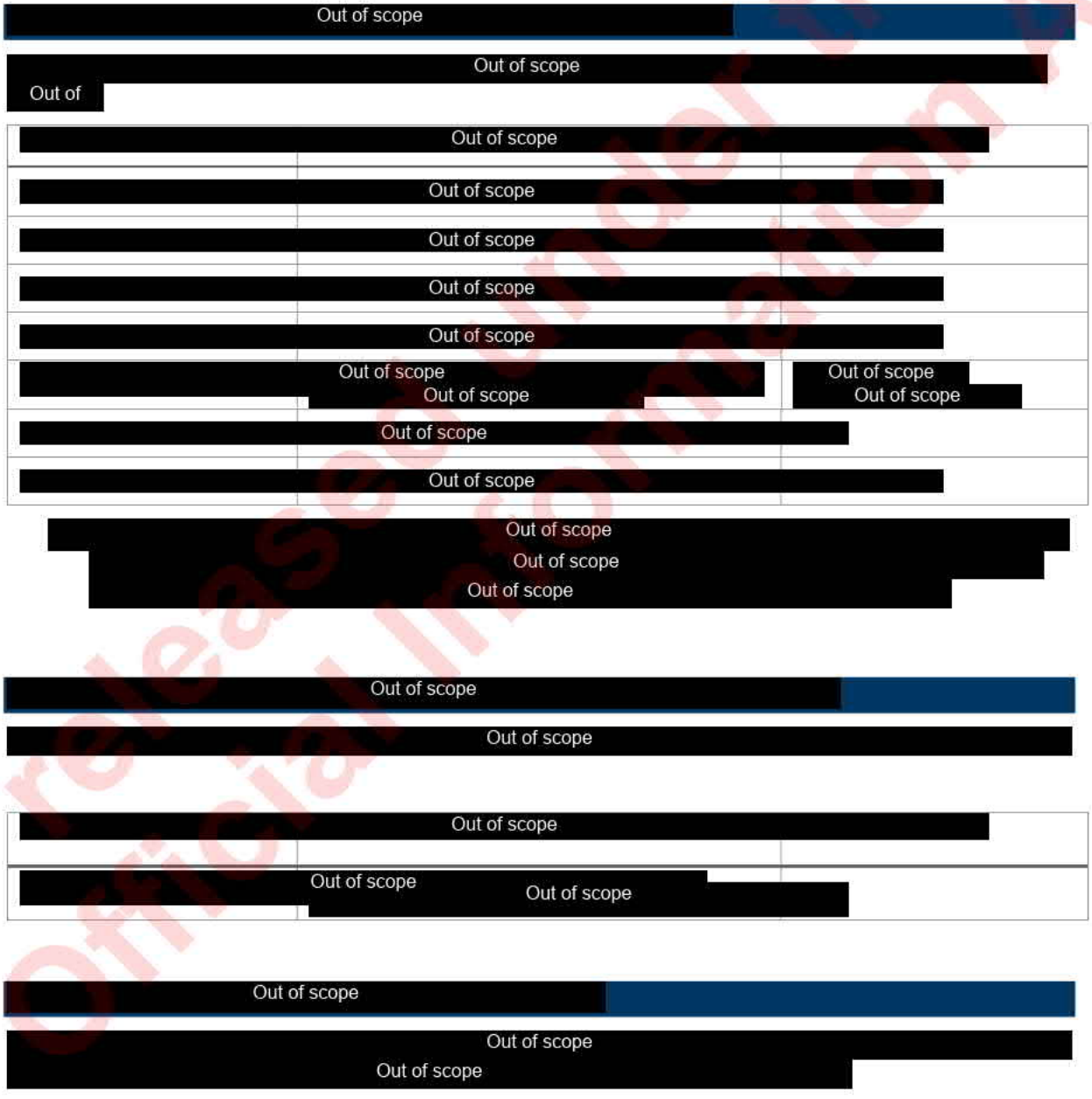
Adam McRae	Senior Implementation Lead
Adrienne Martin	Senior Therapeutic Group Manager/Team Leader
Andrew Oliver	Therapeutic Group Manager
Angie Enoka	Principal Adviser, Pacific
Ben Campbell-Macdonald	Manager, Health Economics
Beth Caudwell	Funding Application Advisor
Caroline De Luca	Senior Therapeutic Group Manager/Team Leader
Casim Alabere	Funding Coordinator
Catherine Kingsbury	Funding Coordinator
Catherine Proffitt	Strategic Planning & Performance Manager
Danae Staples Moon	Senior Therapeutic Group Manager
Denise Mundy	Senior Adviser, Devices Strategy & Development
Elena Saunders	Therapeutic Group Manager
Elliot English	Senior Analyst
Emma Clarke	Tender Analyst / Funding Application Advisor
Geraldine MacGibbon	Manager, Pharmaceutical Funding
Geoff Lawn	Business Architect
Georgia Cassidy	Funding Coordinator
Gregory Evans	Medical Advisory Registrar
Hannah Tibble-Gotz	Pharmaceutical Enquiries Management
Hayden Spencer	Senior Health Economist
Imani Ram	Panel Coordinator
Jason Arnold	Principal Analyst, Access Equity
Josh Wiles	Procurement Manager
Karen Jacobs-Grant	Senior Advisor Māori Responsiveness
Laura Baker	Therapeutic Group Manager
Logan Heyes	Therapeutic Group Manager
Mark Woodard	Director of Corporate Services
Melody Willis	Team Assistant/Project Administrator
Nathan Fox	Senior Health Economist
Peter Murray	Deputy Medical Director
Rachel Grocott	Senior Health Economist
Rachel Watt	Senior Policy Analyst
Rochelle West	Senior Funding Coordinator/Team Leader
Sandy Bhawan	Acting Manager, Access Equity
Sarita Von Afehlt	Therapeutic Group Manager

Scott Metcalfe	Chief Adviser Population Medicine/Deputy Medical Director
Tal Sharrock	Health Economist
Toni Broome	Panel Coordinator
Vivienne Rijnberg	Health Economist

Note: attendees may not have been present for the full duration of the meeting

Material considered

1. Meeting agenda
2. PHARMAC factors for consideration
3 Health need charts
4. Cost effectiveness chart
5. Government priorities
6 Full proposal summaries
7. Proposed additions to the Cost Neutral or Cost Saving list and the Recommended for Decline list
8 Projected budget boundaries



Freestyle Libre Flash Glucose Monitoring System – Type 1 diabetes (patients aged under 18 years requiring repeat inpatient care for hypoglycaemia and patients who are pregnant, breastfeeding or actively planning pregnancy).

Staff considered the information provided and noted the groups included in the defined T1DM patient sub-group. The meeting noted the potential fiscal risk given the current ambiguity of special authority access criteria, in particular the implications of ceasing treatment at 18 years of age and for women who access treatment whilst pregnant (or planning pregnancy) and are required to cease treatment after childbirth The meeting noted the lack of evidence indicating that this method results in better health outcomes, such as reduction of hospitalisations resulting from hypoglycaemic episodes or chronic hyperglycaemia related comorbidity. It was also noted that the system is considered more suitable for many patients than prick tests scripts, although there is uncertainty regarding the benefit to patients and parents in terms of glucose control and whether the additional information the meter provides further stress The meeting also noted the size of the Supplier claimed incremental quality of life gain associated with using flash glucose monitoring versus current finger prick based testing was uncertain Staff noted that type 1 diabetes is less prevalent in Māori, but there are greater complications in Māori for those who develop type 1 diabetes.

Freestyle Libre Flash Glucose Monitoring System Type 1 diabetes was ranked With on the *Options for Investment* list, above Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j), on basis of

cost effectiveness, Government priorities, and suitability, and below Withheld under section 9(2)(b)(ii), Withheld under section 9(2)(b), on basis of lower health need and cost-effectiveness.

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Final review and confirmation of rankings

Staff confirmed the rankings of all the proposals on the Options for Investment list.

Explanation of the PHARMAC Options for Investment list

The Options for Investment list records the relative ranking of proposals for investment, to be progressed when it is affordable and practical to do so The list contains proposals that have health gains and have sufficient information to be prioritised using PHARMAC's Factors for Consideration. Proposals can then be compared with each other to derive a relative ranking for investment. An explanation of the columns in the list follows:

Priority The ranking of proposals within the Options for Investment list.

Proposal The name of the product, or a description of the group of products

Indication A general description of the restrictions that the product would be funded for or widened to. The actual restrictions placed on a funded proposal may be more detailed

PTAC priority Latest clinical recommendation, usually high, medium, low, or decline. Represents PTAC's overall opinion of the proposal with respect to all of the Factors for Consideration. Subcommittee recommendations are marked as such

Health Need – A proxy measure of the Health Need of the average patient, being estimated numbers of Quality Adjusted Life Years lost because of the condition, over a full lifetime under standard care.

QALYs per $1m Cost effectiveness results are presented as ranges to capture the uncertainty in input variables. The likely range represents PHARMAC's best estimate of cost-effectiveness. The possible range, shown in brackets, captures more of the uncertainty in the analysis and is obtained by varying more inputs and over a wider range

5-year NPV to the HML – the cost to the Hospital Medicines Budget over the first five years of listing (net present value, discounted at 8% p.a.). Note that this is reported as a separate column despite the HML and other Pharmaceutical Budgets being merged effective 1 May 2018.

5-year NPV to the CPB the cost to the Combined Pharmaceutical Budget over the first five years of listing (net present value, discounted at 8% p.a.), excluding costs in the HML column.

HML cost first 12 months the cost to the Hospital Medicines Budget in the 2019/20 fiscal year, assuming the earliest possible listing date.

CPB cost first 12 months the cost to the rest of the Combined Pharmaceutical Budget in the 2019/20 fiscal year, assuming the earliest possible listing date.

Cumulative Pharmaceutical Cost (HML+CPB) impact on 2019/20 This column shows the estimated total budget impact (CBP+HML) in the 2019/20 financial year, it counts all proposals up to and including the current row. Each proposal's impact on the cumulative expenditure depends on how soon it could practically be funded, with proposals that begin later in the year having less impact At the time of the meeting, we estimated that if a proposal was not already being consulted on, then the earliest it could be funded would be December 2nd, 2019 Proposals that have known reasons for later listing dates have less impact on the 2019/20 fiscal year.

New proposals are in **bolded blue**. Updated proposals are in **bolded blue and begin with *RR*.**

PHARMAC's Options for Investment list ranked by Factors for Consideration, as at 10th December 2019

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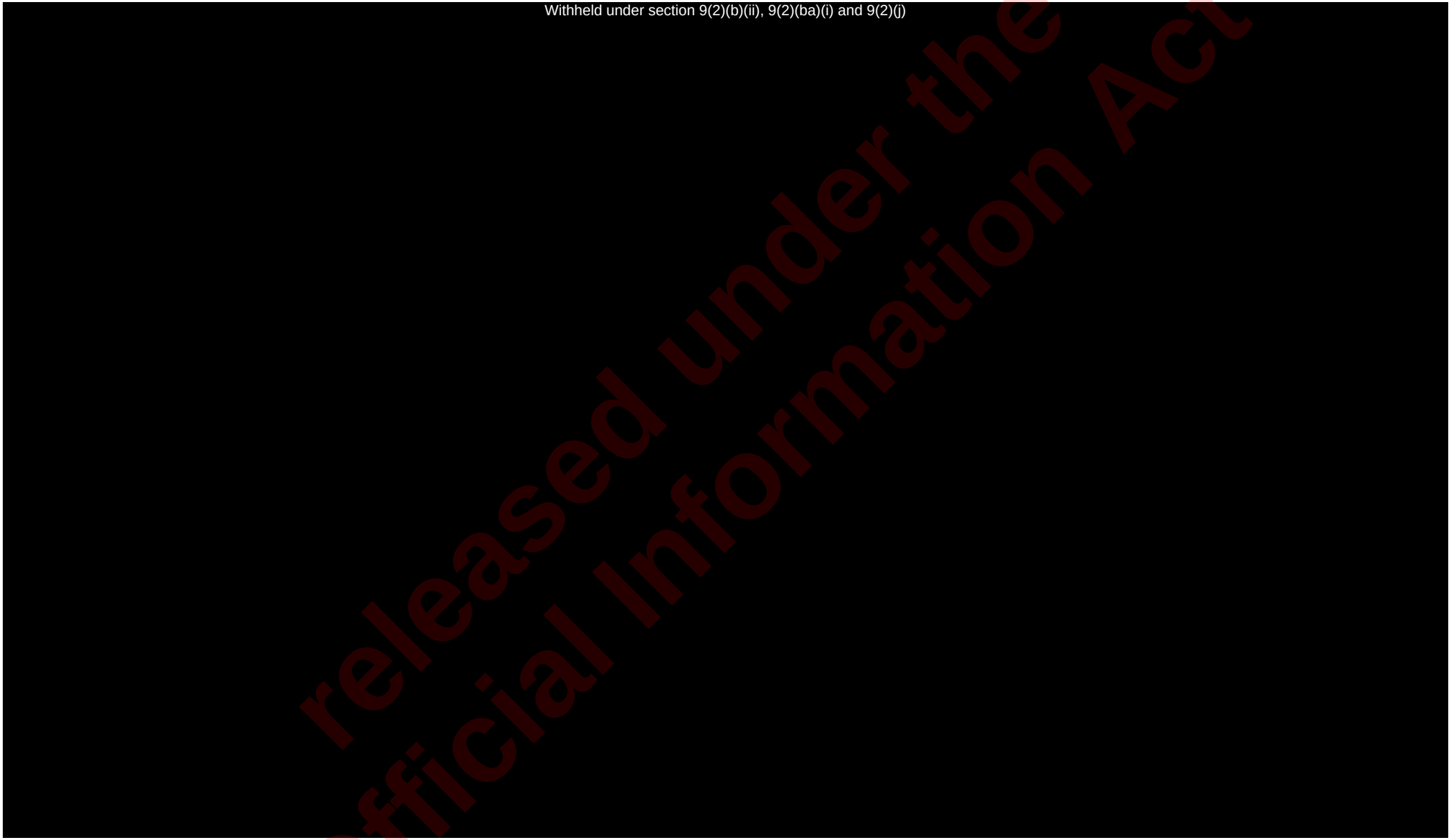

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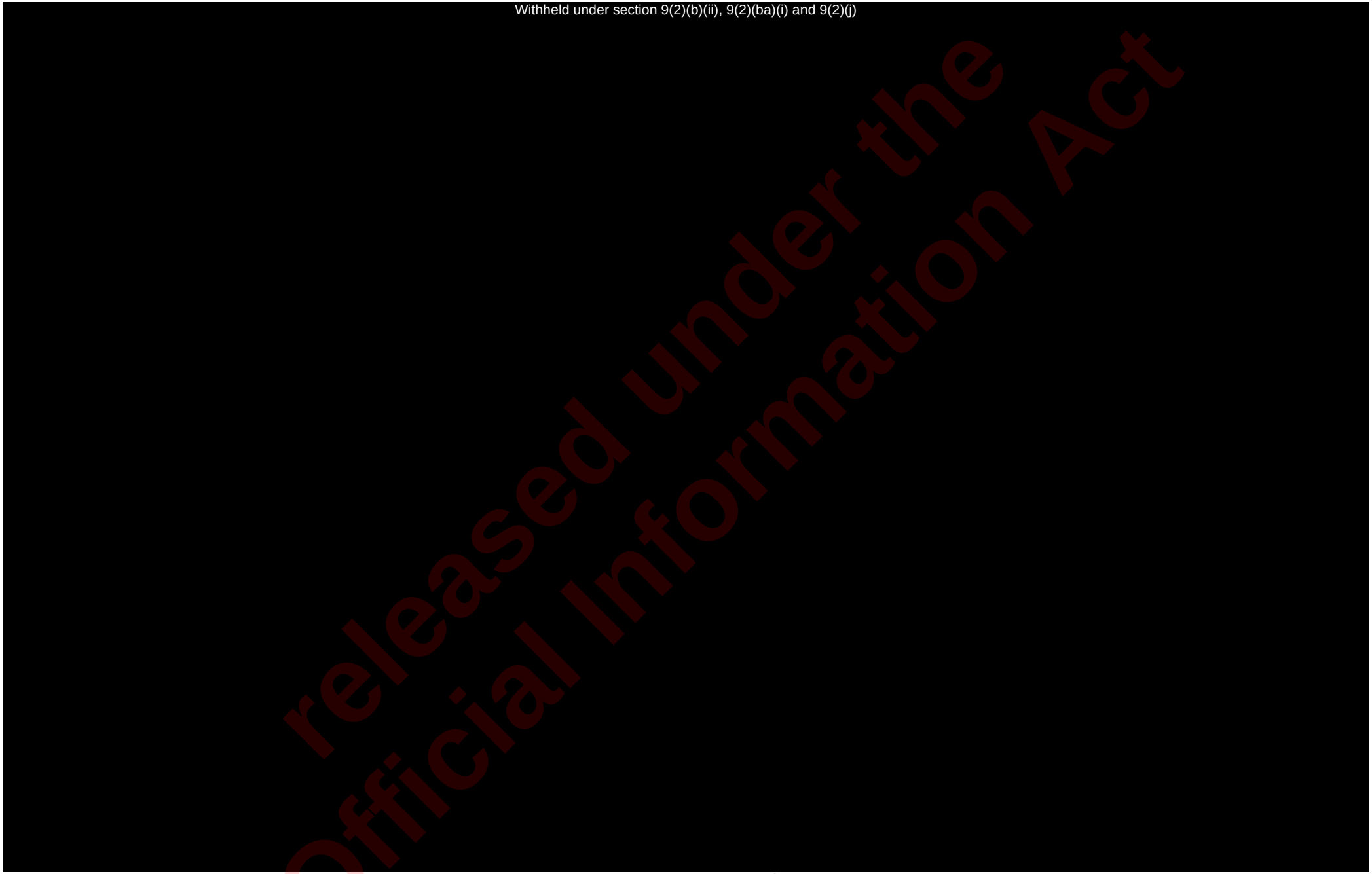

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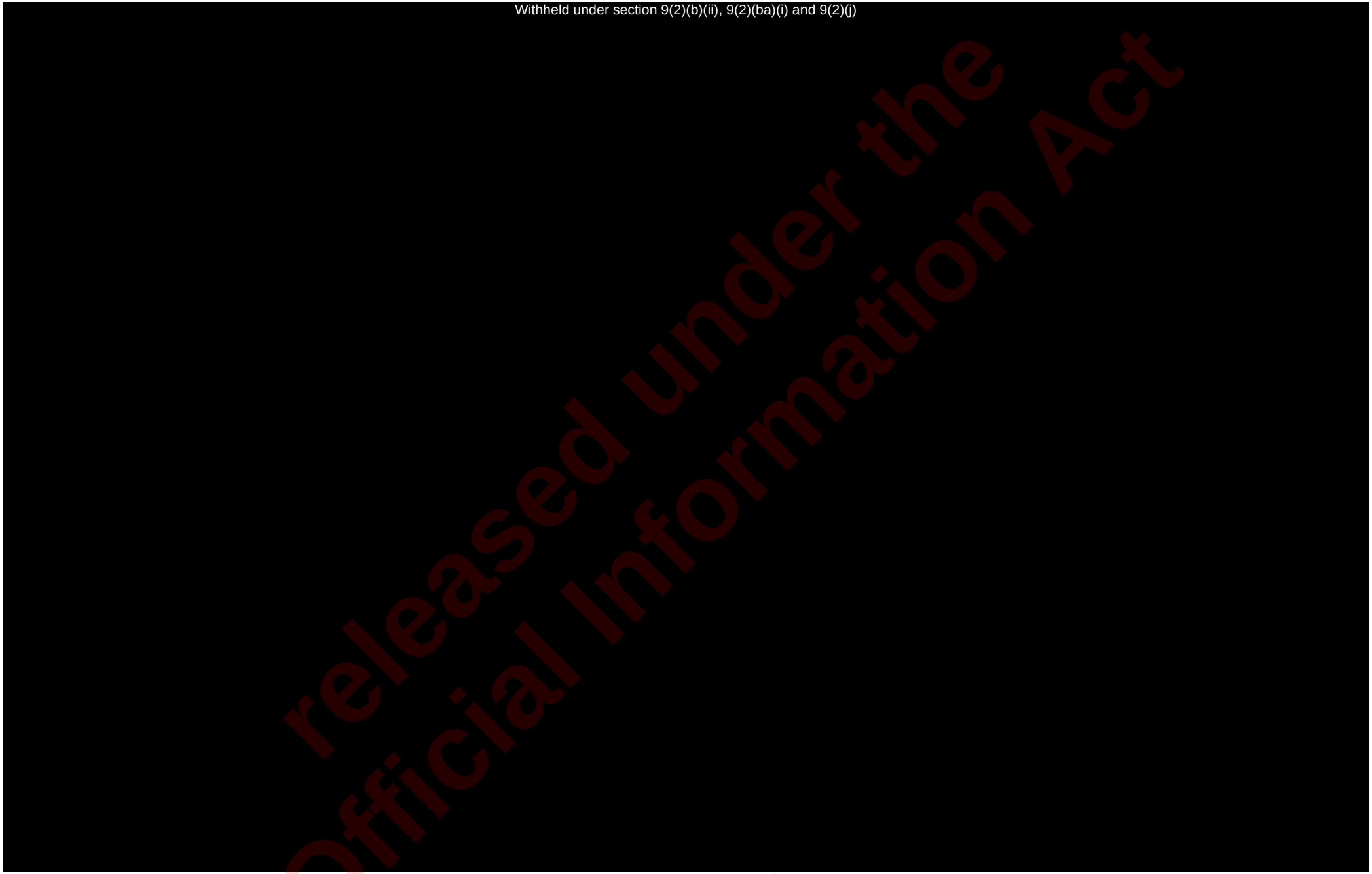

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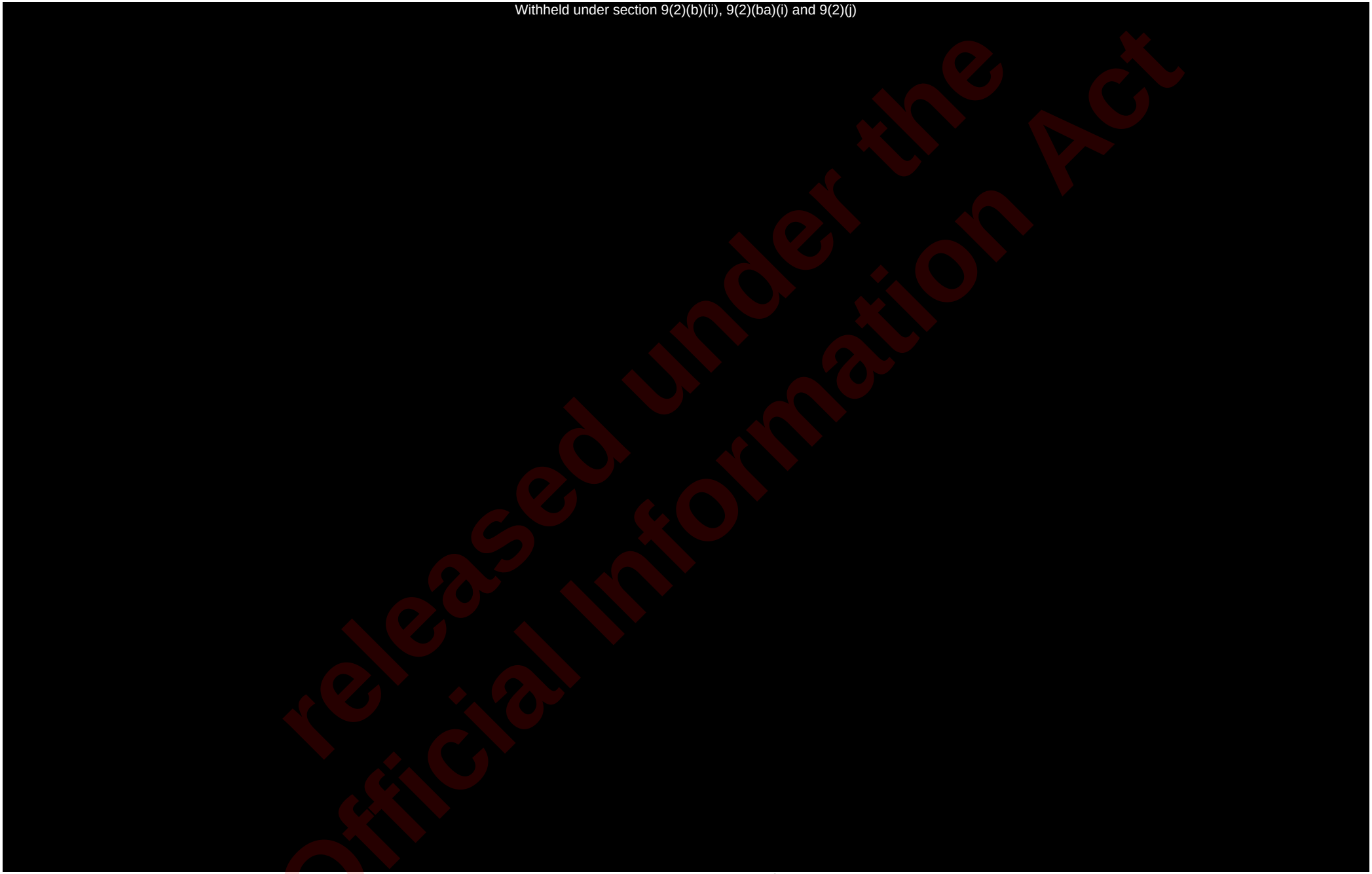

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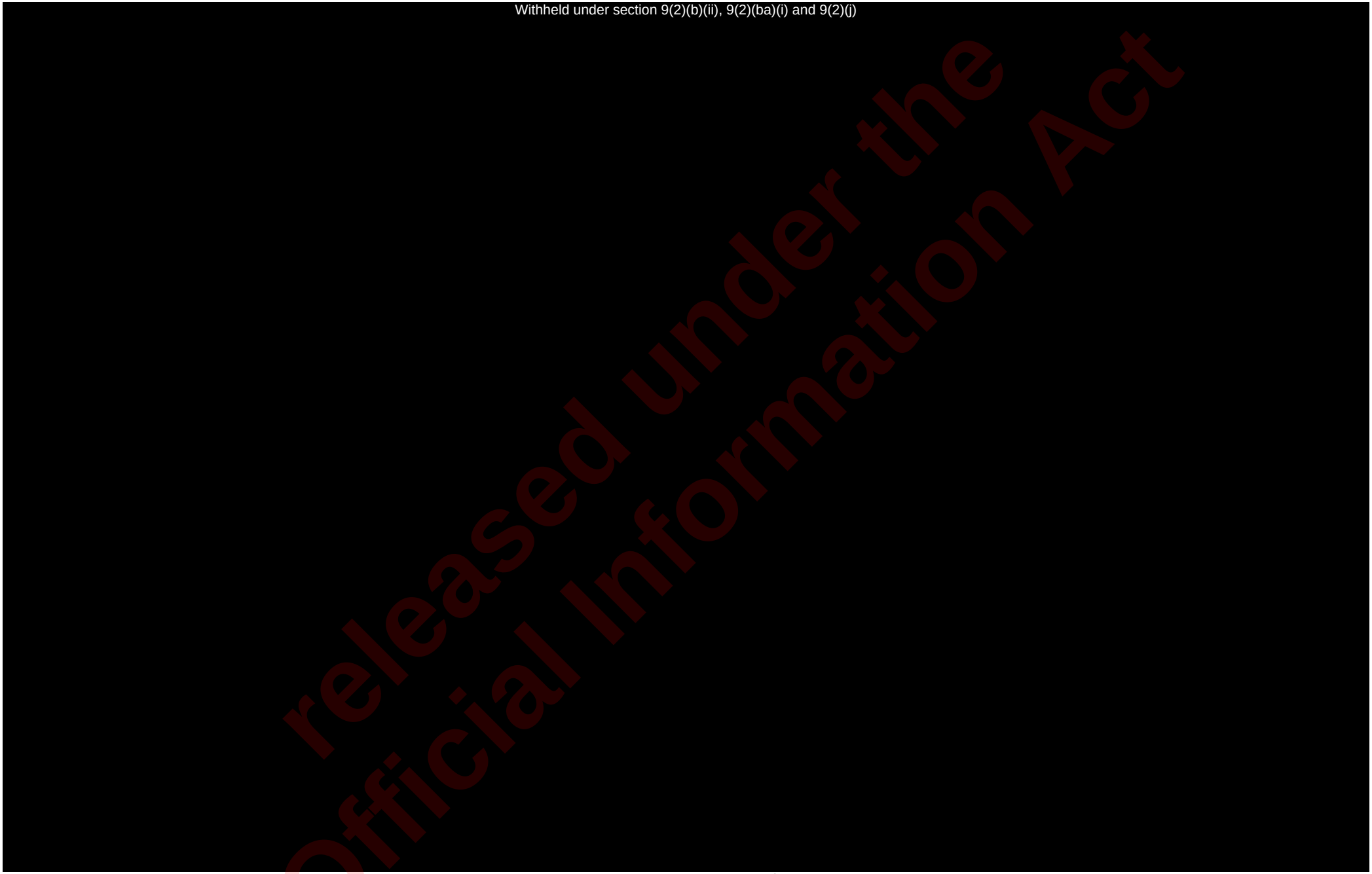

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PHARMAC
Pharmaceutical Management Agency

Prioritisation Paper

Prioritisation Meeting to be held at the PHARMAC Office on

Tuesday 3 March 2020

Contents

In addition to the Prioritisation meeting agenda document, please refer to the following sections of this paper for information on new proposals, proposals currently ranked on the *Option for Investment* list and key consideration documentation.

Section 1: Prioritisation meeting format

The quarterly prioritisation meeting is a key step in PHARMAC's decision processes, where each current funding proposal is considered and ranked using the Factors for Consideration.

Formally, PHARMAC's assessment of funding proposals is a 'deliberative process', whereby all relevant different points of view are considered and traded off against one another. This contrasts with systems that use predetermined weights for each criterion

In a deliberative process, it is critical that all perspectives are considered by all people involved in the consensus decision This means that all meeting participants should have good opportunity to make sure that key points are heard and that they hear and understand the points raised from other perspectives.

This document includes only brief summaries of information about each proposal; for full details please refer to the relevant Technology Assessment Report and PTAC minutes.

Below is the protocol to structure the staff discussions during the prioritisation meeting. It builds on a successful process that PHARMAC has developed over many years, while giving it more structure as appropriate to the large group involved in each meeting.

Speaking order

Therapeutic Group Manager	Introduces item. Key therapeutic and commercial issues. Why is it being prioritised today?
Health Economist	Introduce the information collected against each of the Factors for Consideration, and cost-effectiveness. Are any of them unusual, contentious, or particularly uncertain? Explain the key drivers of the cost-effectiveness result. Explain the range of cost effectiveness estimates
Medical Directorate	Any other relevant clinical issues not yet raised
Whakarata Māori	Opportunity to comment on any particular issues for Māori, including health need and ability to benefit
Analysis	Opportunity for comment on the patient numbers, the budget impact, and any other relevant financial issues.
Policy	Are there any unusual policy issues raised by this proposal?
Access and equity	Opportunity to comment on the impact of a proposal if funded on equity and access issues
All staff	All staff are encouraged to question or comment on any of the issues raised during the discussion so far.
Chair	Ranking: given the discussion, should the proposal be moved up or down the prioritisation list?

Section 2: Factors for consideration

Factors are presented here in the order they are listed in decision papers, without implying any ranking or relative importance.

Need

- The health need of the person
- The availability and suitability of existing medicines, medical devices and treatments
- The health need of family, whānau, and wider society
- The impact on the Māori health areas of focus and Māori health outcomes
- The impact on the health outcomes of population groups experiencing health disparities
- Government Health Condition Priorities

Health Benefits

- The health benefit to the person
- The health benefit to family, whānau and wider society
- Consequences for the health system
- Government Health System Priorities

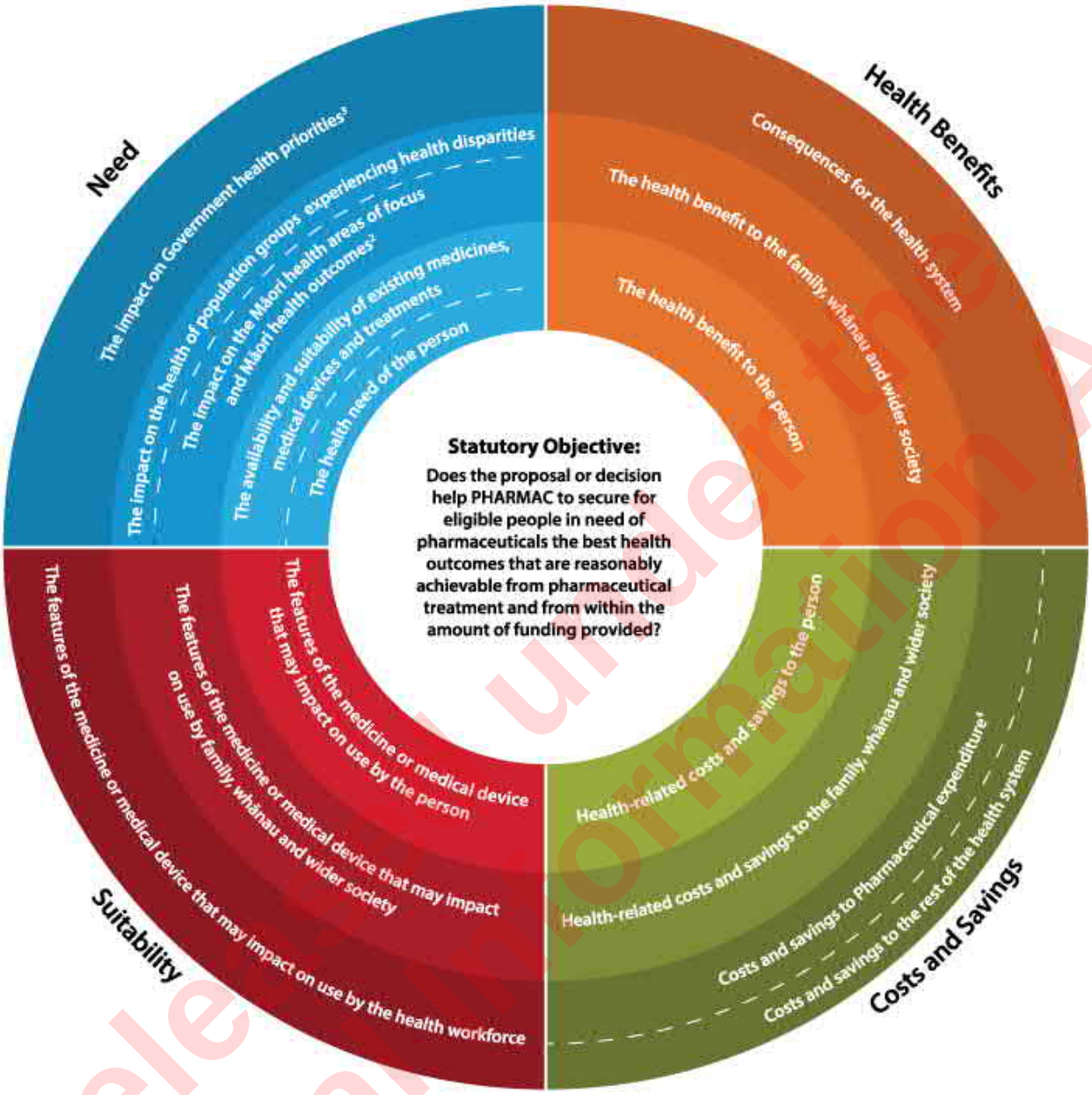
Suitability

- The features of the medicine or medical device that impact on use by the person
- The features of the medicine or medical device that impact on use by family, whānau and wider society
- The features of the medicine or medical device that impact on use by the health workforce

Costs and Savings

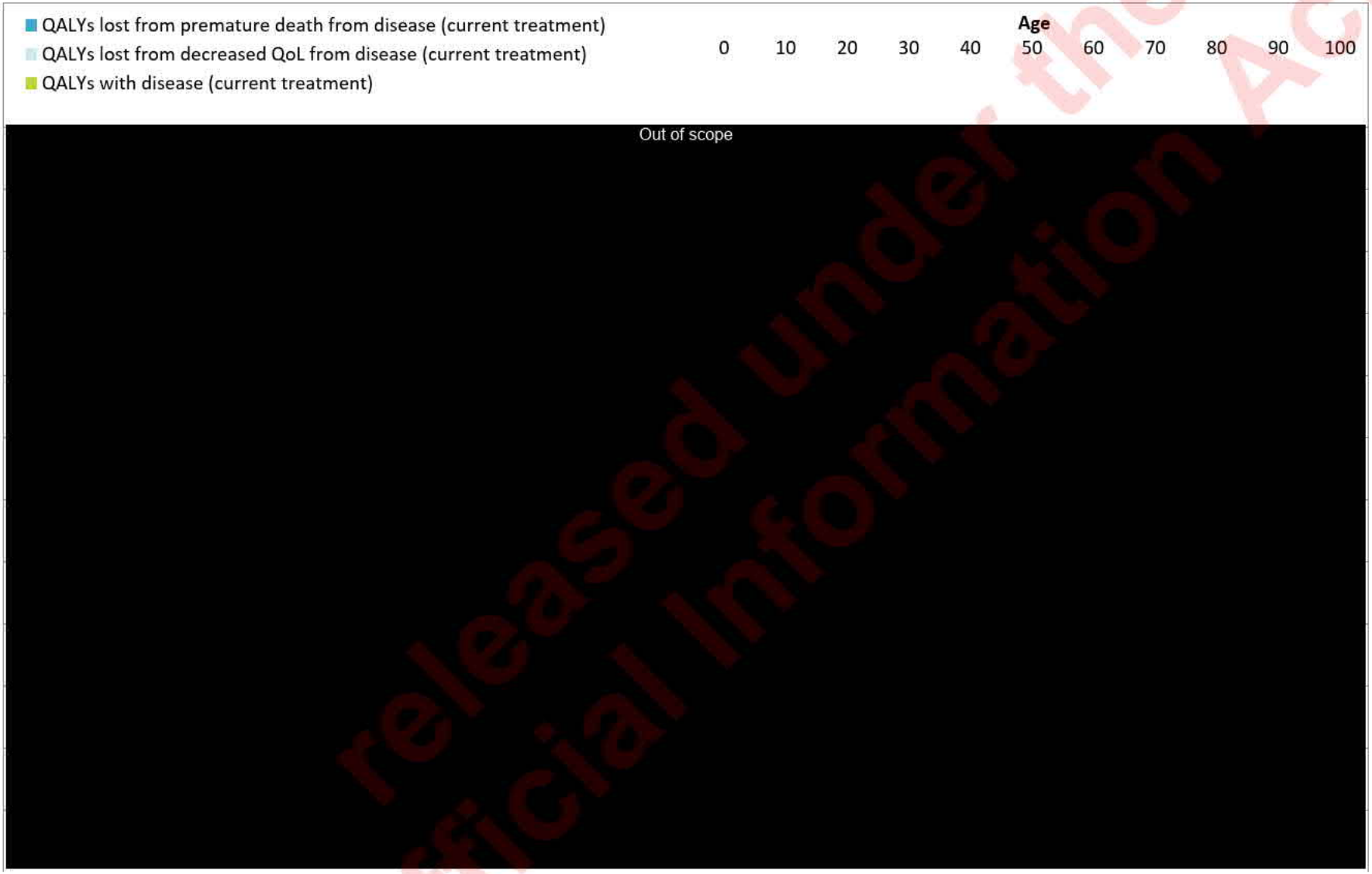
- Health related costs and savings to the person
- Health-related costs and savings to the family, whānau and wider society
- Costs and savings to pharmaceutical expenditure
- Costs and savings to the rest of the health system

Figure 1: PHARMAC Factors for Consideration



Section 3: Health Need.

These graphs show estimates of the health loss experienced by an average or typical patient in the relevant cohort with currently funded treatments for treatments on the current prioritisation list They do not reflect the effect of the new products under consideration Each bar starts at the average age of onset of the specific disorder in question. Absolute values are shown in a separate table.



Out of scope

Freestyle Libre Flash Glucose	Type 1 diabetes	

Out of scope

Table 1: Lifetime Health Need associated with conditions

Drug	Indication	Lifetime QALYs lost
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Freestyle Libre Flash Glucose Monitoring System	Type 1 diabetes	18

Section 4: Cost effectiveness

Previously ranked proposals are shown in existing priority order New proposals are placed roughly within the list as a starting point only. Cost effectiveness ranges (0 to 70 QALYs per $1m) may extend off the chart; proposals that are completely off the chart or cost-saving/cost neutral are detailed in the table on the next page; proposals with ranges within 0 to 70 QALYs per $1m and extending outside are providing in both the chart and the table

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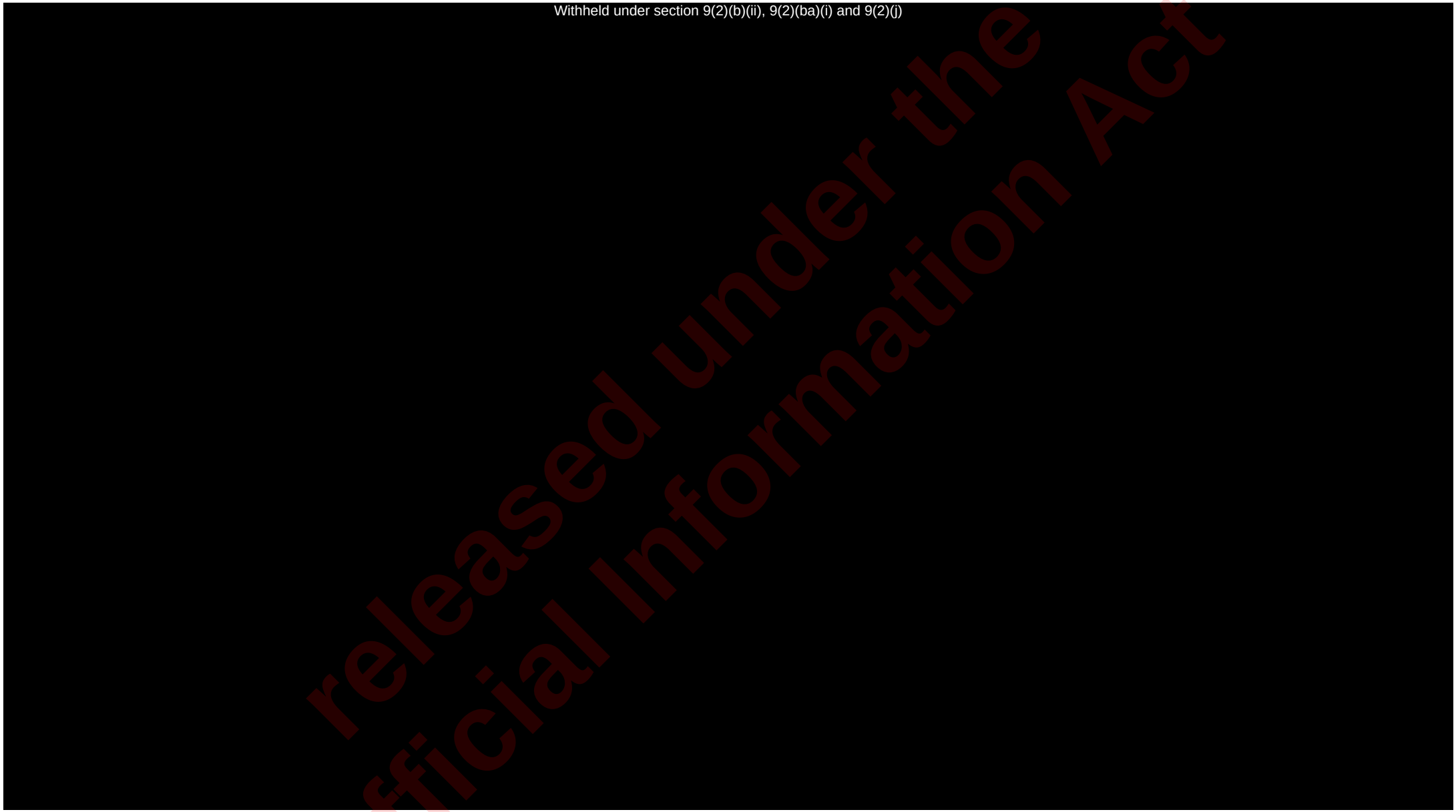

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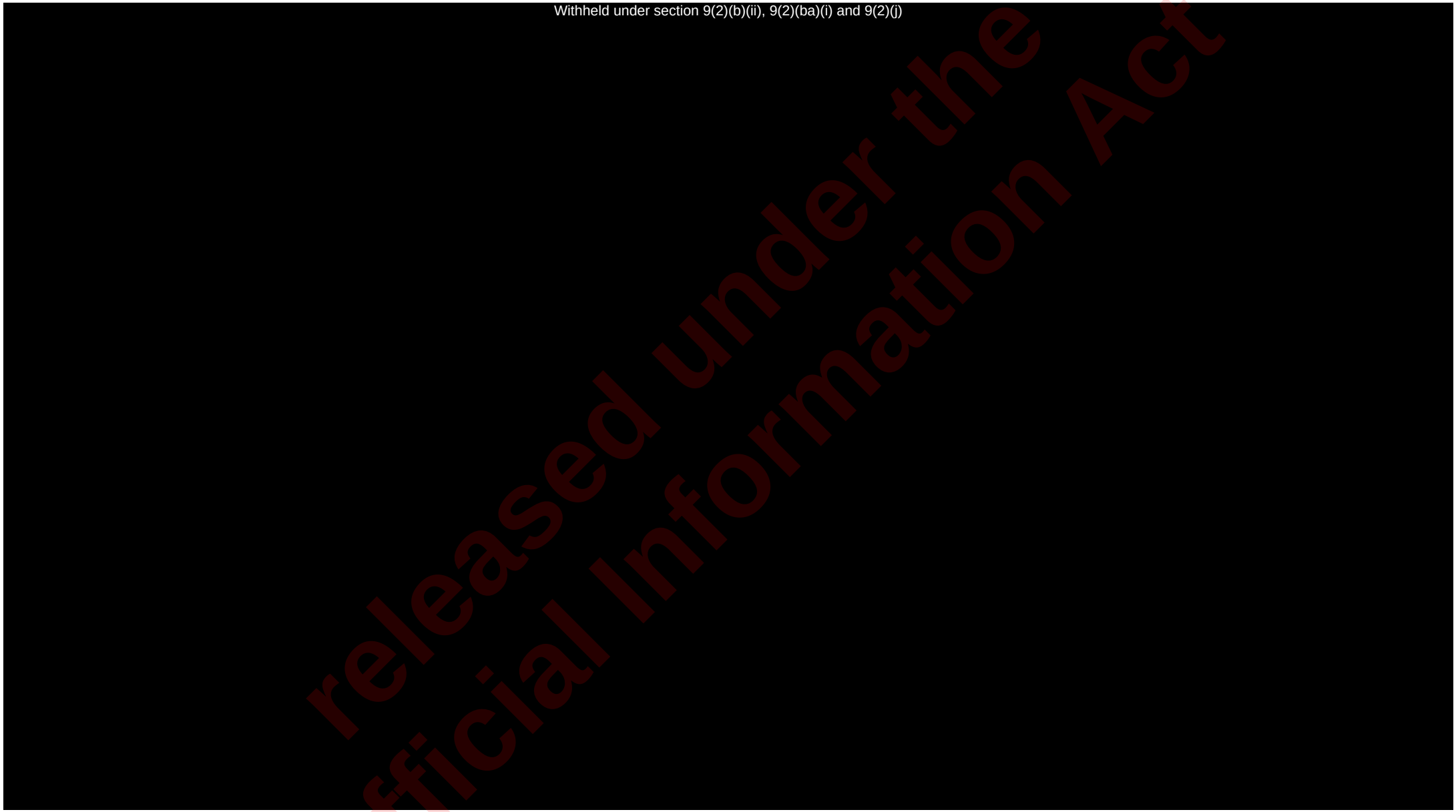

Table 2 Proposals where cost effectiveness may be more than 70 QALYs per $1 million

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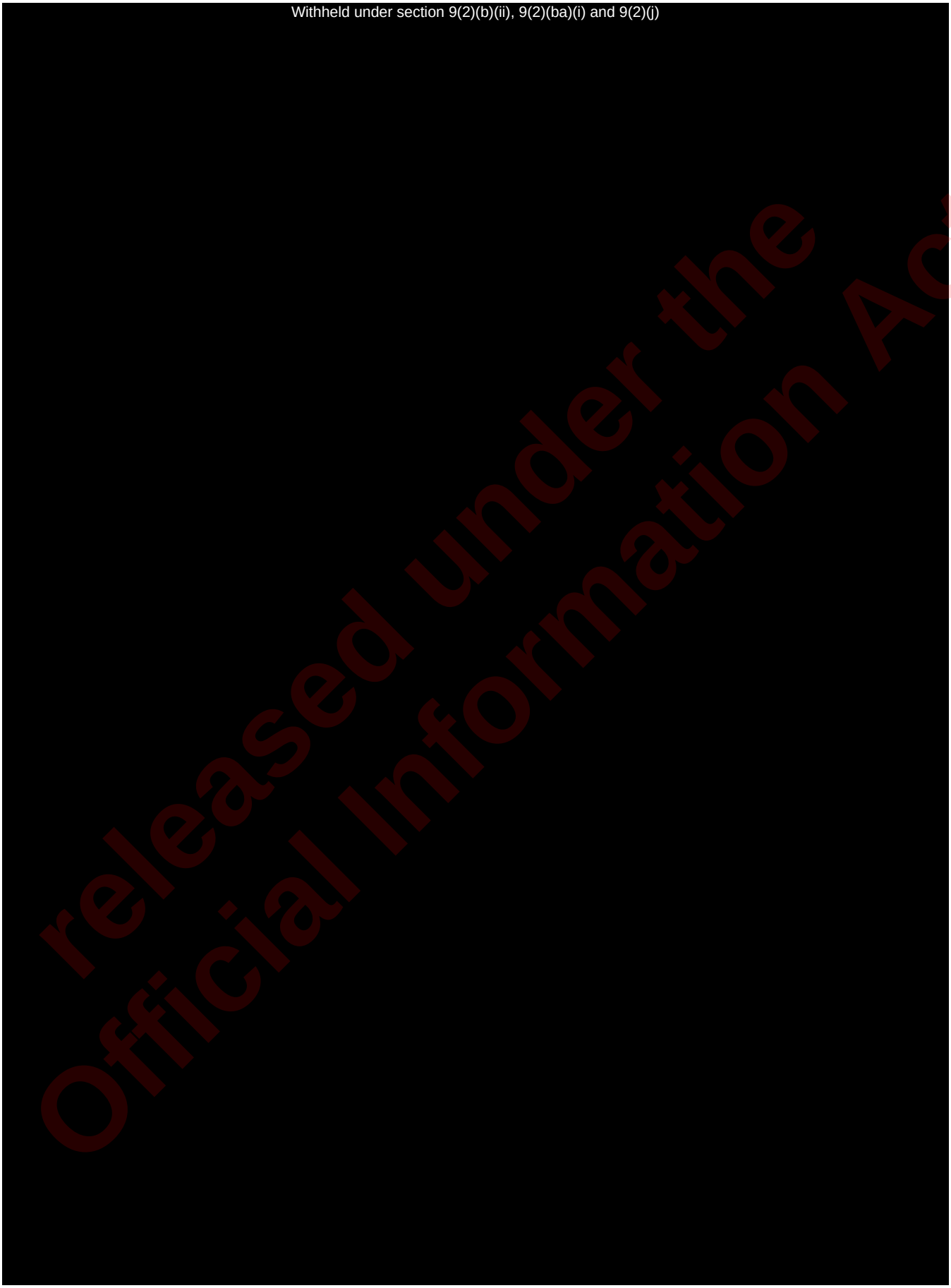

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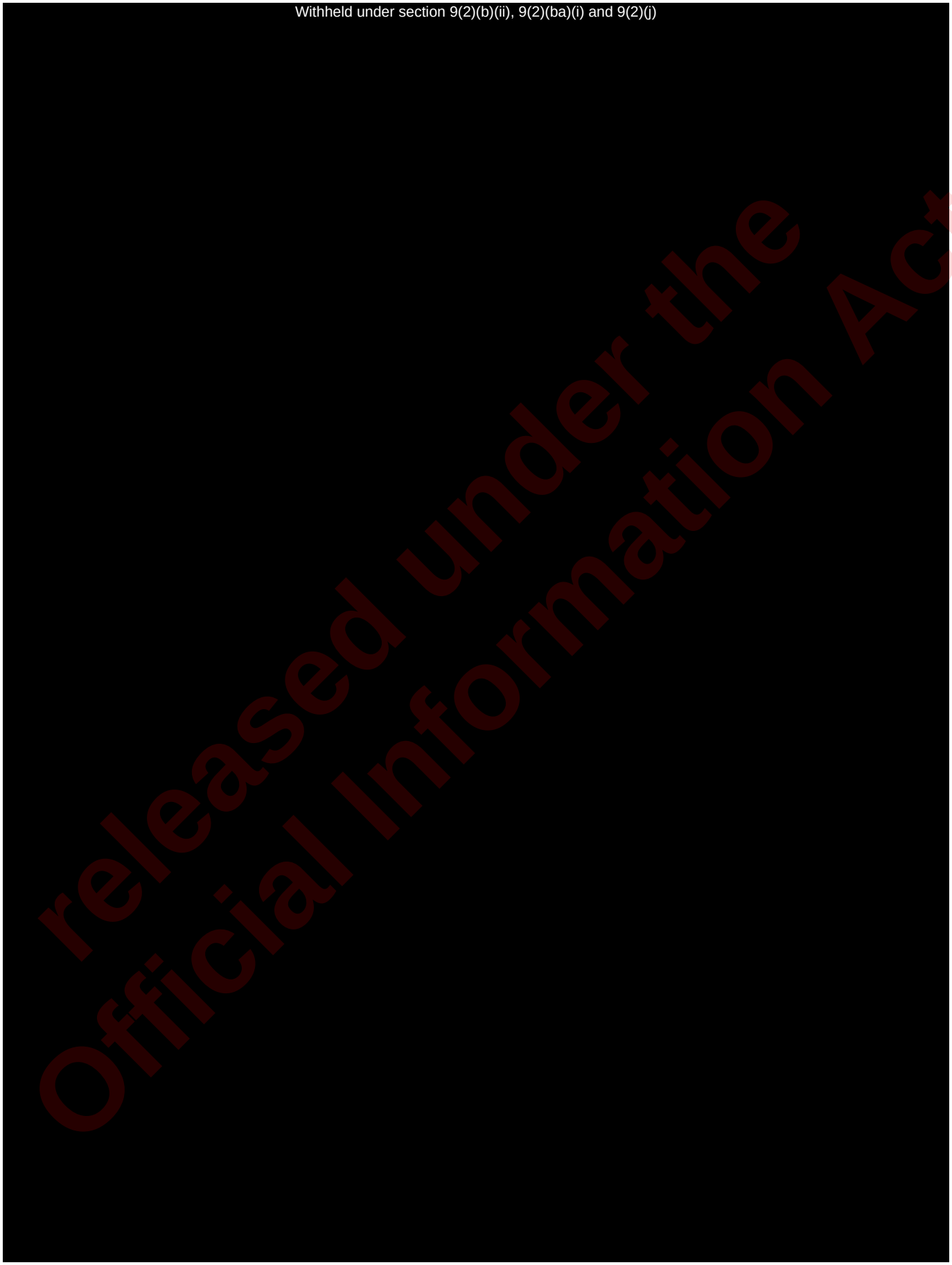

Section 5: Government health priorities

The impact on government health priorities

This factor asks whether the disease, condition, or illness is a Government health priority.

Last updated: September 2018

Disease, illness or condition	Interpretation for FFC
Alcohol and or drug addiction	Minimises harm from alcohol and drug dependence
Dementia and frailty	Reduces impact of dementia and frailty
End of life	Supports provision of high quality palliative care
Foetal Alcohol Spectrum Disorder	Reduces incidence of foetal alcohol spectrum disorders
Infectious diseases	Reduces transmission of infectious diseases, especially amongst those with newborn babies
Learning/ intellectual disabilities	Improves the health of people with learning or intellectual disabilities
Long term conditions	Helps prevention, intervention, rehabilitation and wellbeing of people with LTCs
Mental health with a focus on youth, pregnant and postnatal women	Supports people to improve their mental health and / or address addiction, including: • pregnant or postnatal women experiencing mental health, alcohol and other drug conditions young people with, or at risk of developing, mild to moderate mental health issues
Obesity	Helps prevent or reduce obesity
Smoking cessation	Reduces smoking rates/Helps people to stop smoking

Consequences for the health system

The Government sets various goals for the health system. PHARMAC's decisions should consider whether and how its actions might support the Government's strategic intentions for the health system.

Last updated: September 2018

Health system priority	Interpretation for FFC
Antimicrobial resistance	Supports optimal use of antimicrobials and minimises the emergence of antimicrobial resistance
Closer to home / Making services more accessible, including shifting services	Supports integrated care Treatment can be provided more conveniently to patients.
Health equity	Enhances equitable health access and/or outcomes.
Increased immunisations	Increases immunisations/Improves prevention and ensures immunisation courses administered on time.
Supports the health of older people	Supports older people to stay healthy and independent and live well with long term conditions Reduces unnecessary acute admissions. Reduces inappropriate polypharmacy.
Supporting people to be 'health smart'	Supports best use of pharmaceuticals

Section: 6: Proposal Summaries

This section has a dossier for each proposal on the Options for Investment list Where multiple proposals are represented by one item, please refer to the name of the item.

When data are not given for a Factor, the following terms are used:

No difference: Evidence found that shows no material difference or effect.
None identified: Staff searched for relevant evidence and found none
Not reviewed: Staff did not seek information on this Factor

For more information on any proposal, refer to the Technology Assessment Report, to the relevant Objective file, or to the proposal's records in PharSight.

If you are reading this document on screen, select the Word menu option **View | Navigation Pane** Click on the dossier's name to jump to the page

Freestyle Libre Flash Glucose Monitoring System-Type 1 diabetes

Latest Clinical Recommendation: No Formal Recommendation from PTAC, 23/05/2019

Comparator: Finger prick blood glucose (FPBG) monitoring via a blood glucose meter.

NEED

Condition: Type 1 diabetes mellitus is a chronic disease resulting from the autoimmune destruction of pancreatic beta cells resulting in insulin deficiency. Loss of endogenous insulin can lead to hyperglycemia and life threatening ketoacidosis

Health need of the person: 18

Insulin is used to prevent severe hyperglycemia and ketoacidosis, but maintaining glucose levels within the normal range is difficult Over treatment results in hypoglycemia, which can range from mild and uncomfortable to life threatening

Health Need Of Family Whānau and Others: Evidence is emerging of significant caregiver stress among parents of children and adolescents with type-1 diabetes (Grover et al. Perspect Clin Res. 2016;7(1):32-39). The evidence is unclear regarding whether increased monitoring using the newer technology increases or reduces caregiver stress.

Availability of existing alternatives:

Self-monitor using a blood glucose meter between 4 to 10 times per day (finger-prick).

Māori Health Areas of Focus:

Māori health need:

Impact on population groups experiencing disparities:none identified

Government condition priorities:

HEALTH BENEFITS

Health benefit to the person: QALYs gained per person (lifetime NPV @3 5%)

Health benefit to family, whanau: QALYs gained per person treated (lifetime NPV @3.5%). Probable reduction in caregiver stress resulting from remote monitoring of blood glucose levels via the Freestyle device. This is likely to be even more so overnight when the current method requires waking a child and undertaking a finger prick. Furthermore, the device may allow carers more freedom to leave the patient in the care of others Conversely, some data indicates that the increased granularity of data available can increase the burden of stress to carers.

Health benefit to others: QALYs gained per person treated (lifetime NPV @3 5%) Probable reduction in stress for teachers / teacher aides who are involved in the daily care of children and adolescents whilst they are at school.

Consequences for health system:

Freestyle libre flash glucose monitoring system could conceivably reduce the number of required emergency department admissions, and the number of diabetes related complications requiring treatment via the health system The exact impact is unknown

Government system priorities:

COSTS AND SAVINGS (Lifetime NPV @3.5%).

Health costs to the person: Incremental costs
A $5 prescription co pay will apply every three months.

Health costs to family, whanau, others: Incremental costs
Not relevant.

Pharmaceutical costs per person: Incremental costs
Withheld per person per year compared to Withh for the current standard of care.

Costs to rest of health sector, per person: Incremental costs
4% net distribution costs will apply to this device Note, no gross pricing has been provided by the supplier in their proposal

Total incremental costs per person (NPV): =

SUITABILITY

Impact on use by the person: Freestyle libre flash glucose monitoring system involves application once every 14 days, involving one small prick. This compares to the current SMBG method, which can involve up to 10 pricks per day. F'style provides near continuous data readings

Impact on use by others: Device enables remote monitoring of blood glucose via bluetooth uplink to multiple smart mobile devices.

Impact on health workforce: Additional data availability may impact on clinical services, increasing the clinic time required to train individual on the use of the device as well as finger prick testing (which will still be required) and for the interpretation of a larger volu data

COST EFFECTIVENESS

Point estimate = Wit QALYs per $1m
Likely range Withheld QALYs per $1m.
Possible range Withheld QALYs per $1m.

BUDGET IMPACT

Year	1	2	3	4	5
Patients	0	0	0	0	0
Cost to patients, family, whānau	$0.00	$0.00	$0.00	$0.00	$0.00
Pharmaceutical costs	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit
Other health sector costs	$410,000 00	$580,000 00	$680,000 00	$720,000 00	$750,000 00
Total Health Sector Budget Impact	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit	Withheld under section 9(2)(b)(ii) Wit

Clinical advice indicates that an increase to clinic time per patient is likely due to the increase in data generated by FreeStyle libre. This cost has been unaccounted for in this BIA.