LEGAL ADVICE

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Hon David Parker, Attorney-General

Consistency with the New Zealand Bill of Rights Act 1990: New Zealand Public Health and Disability (Restriction on Crown Funding Agreements and Unfunded Cancer Medicines) Amendment Bill

Purpose

1. We have considered whether the New Zealand Public Health and Disability (Restriction on Crown Funding Agreements and Unfunded Cancer Medicines) Amendment Bill (the Bill) a member's Bill in the name of Dr Shane Reti MP is consistent with the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990 (the Bill of Rights Act).

2. We have concluded that the Bill appears to be consistent with the right to freedom from discrimination, as affirmed in s 19 of the Bill of Rights Act. Our analysis is set out below.

The Bill

3. Generally, if a person purchases a medicine not funded by Pharmac (an unfunded medicine) which needs to be administered by a doctor or nurse, that person must go to a private hospital and pay to have the medicine administered.[1]

4. The Bill's stated objective is to improve access to public medical care for cancer patients who purchase unfunded cancer medicines that require administration in a hospital setting.

5. The Explanatory note states that many cancer medicines not funded by Pharmac cannot be administered in the public health system under the current legislative framework.[2] Further, administration costs of an unfunded cancer medicine can sometimes be as much as the medicine itself in terms of the cost of day-stay administration of that medicine in private fee-paying facilities.

6. The Bill aims to share the burden of cost between patients and the Crown, where both parties contribute to overall cancer care for unfunded cancer medicines. The Bill amends the New Zealand Public Health and Disability Act 2000 (the NZPHD Act) to provide that a Crown funding agreement (CFA) must not contain any term or condition that has the effect of prohibiting a DHB from providing health services related to the administration of a pharmaceutical to a person who has purchased the pharmaceutical privately, if:

[1] There may be a number of reasons why a person needs to purchase an unfunded medicine (if it is prescribed), such as where a publicly funded medicine is not effective for that particular person, or a person needs a combination of funded and unfunded medicines for effective treatment.

[2] We note there appears to be a number of publicly funded cancer medicines listed by Pharmac (see further footnote 22). We also understand, if these funded medicines required administration in a public hospital, there would be no charge (see further footnote 7).

a. that person has been prescribed the pharmaceutical for the treatment of cancer by a medical practitioner whose scope of practice includes the treatment of cancer;

b. the pharmaceutical is a medicine approved under the Medicines Act 1981 for the treatment of that cancer;

c. the cost of the pharmaceutical is not subsidised by the Crown for the supply of that pharmaceutical to the person being treated; and

d. the administration of the pharmaceutical requires inpatient, outpatient or day stay medical supervision.

7. The Bill also inserts a definition for 'medical practitioner' modelled on the definition of a health practitioner under the Health Practitioners Competence Assurance Act 2003.

Our view of the Bill's effect

Current position

8. Pharmac manages the purchase of publicly funded medicines for the community and public hospitals, the latter on behalf of DHBs. Medicines may be fully or partly subsidised by Pharmac. Under the NZPHD Act, Pharmac is required to manage a pharmaceutical schedule that lists subsidised medicines and medical treatments, and, in exceptional circumstances, to provide subsidies for pharmaceuticals not on the schedule.[3]

9. Section 23(7) of the NZPHD Act provides that a DHB must not act inconsistently with the pharmaceutical schedule in performing any of its functions in relation to the supply of pharmaceuticals.[4]

10. DHBs enter into a CFA with the Minister of Health under s 10 of the NZPHD Act. The CFA sets out the funding that DHBs will receive in return for providing services to its resident population.[5] The Ministry of Health's operational policy framework, which forms part of the CFA, provides that DHBs 'cannot supplement the pharmaceutical schedule by providing additional pharmaceutical subsidies, or by broadening the availability of listed pharmaceuticals in each case, beyond conditions specified in the schedule'.[6]

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[3] New Zealand Public Health and Disability Act 2000, s 48(a). To provide subsidies in exceptional circumstances, Pharmac has developed the Named Patient Pharmaceutical Assessment Policy (Policy). The Policy provides for applications from individual patients for subsidised access to treatments for their particular clinical circumstances where such treatments are not funded under the pharmaceutical schedule on a population basis. There is also an exception for DHBs to give (and be eligible to receive a subsidy for) any pharmaceutical for use within a paediatric oncology/haematology service for the treatment of cancer. See Pharmac 'Rules of the Schedule' (18 January 2021), accessible at: https://pharmac.govt.nz/pharmaceutical-schedule/general-rules-section-a/#bookmark9, cls 8.1 and 8.2.

[4] New Zealand Public Health and Disability Act 2000, s 23(7). We note that Minister of Health is not able to direct Pharmac to fund any specific medicines at any particular price (s 65(2)).

[5] Ministry of Health 'The New Zealand Health and Disability System: Handbook of Organisations and Responsibilities' (October 2017) at 27. Accessible at: www.health.govt.nz/publication/briefing-incoming-minister-health-2017-new-zealand-health-and-disability-system-organisation.

[6] Unless it is in accordance with the provisions and rules of the pharmaceutical schedule, or relating to the Named Patient Pharmaceutical Assessment Policy (above n 3), see Ministry of Health 'Operational Policy Framework 2021/22' (March 2021), cl 4.14.3(c). The Operational Policy Framework is said to be incorporated as part of the Crown Funding Agreement. Clause 4.14.1 of the Operational Policy Framework states that it clarifies DHBs' duties, in respect of s 23(7) of the New Zealand Public Health and Disability Act 2000, by giving effect to the requirement in s 23(7).

The Bill's effect

11. The Bill prohibits the Crown (the Minister of Health) and DHBs from including a term in the CFA that has the effect of prohibiting a DHB from providing health services related to the administration of unfunded cancer medicine to patients who have been prescribed an approved medicine for cancer treatment.

12. We consider that the Bill's effect could be to enable, but not require, DHBs to exercise their discretion to admit a patient for the administration of a particular unfunded cancer medicine in a particular case. Whether a person would have to pay for the costs of administration in a public hospital under the Bill is not stated, but we consider that would also be in the DHB's discretion.[7] Therefore, we consider that the Bill creates an exception for cancer patients to have their unfunded medicine administered in a public hospital (which otherwise appears not permitted).[8]

Consistency with the Bill of Rights Act

Section 19 – Freedom from Discrimination

13. Section 19(1) of the Bill of Rights Act affirms the right to freedom from discrimination on the prohibited grounds listed in the Human Rights Act 1993. Disability is a prohibited ground of discrimination, and is exhaustively defined as:

    a. Physical disability or impairment;
    b. Physical illness;
    c. Psychiatric illness;
    d. Intellectual or psychological disability or impairment;
    e. Any other loss or abnormality of psychological, physiological, or anatomical structure or function;
    f. Reliance on a guide dog, wheelchair, or other remedial means; and
    g. The presence in the body of organisms capable of causing disease.

14. Discrimination under s 19 of the Bill of Rights Act arises where:[9]

    a. there is differential treatment or effects as between persons or groups in analogous or comparable situations on the basis of a prohibited ground of discrimination; and
    b. that treatment has a discriminatory impact (i.e. it imposes a material disadvantage on the person or group differentiated against).

15. The differential treatment analysis takes a purposive and untechnical approach to avoid artificially ruling out discrimination.[10] Not all differential treatment will be

[7] As we understand, generally inpatient and outpatient treatment at a public hospital are free. See Ministry of Health, 'Hospital visits' (20 November 2008), accessible at: www.health.govt.nz/new-zealand-health-system/publicly-funded-health-and-disability-services/hospital-visits.

[8] In our view, if administration of pharmaceuticals falls within the meaning of the term 'supply' in s 23(7) of the New Zealand Public Health and Disability Act 2000, administering an unfunded medicine could undermine the purpose of the pharmaceutical schedule by broadening the availability of pharmaceuticals beyond those listed in the schedule. We presume that the pharmaceutical schedule would need to be updated to reflect the Bill, such that a DHB would not be acting inconsistently with that schedule, if s 23(7) of that Act currently prevents a DHB from doing this.

[9] *Ministry of Health v Atkinson* [2012] NZCA 184, [2012] 3 NZLR 456 CA at [55].

[10] *Atkinson v Minister of Health* [2010] HRRT 1 at [211] – [212]; *Air New Zealand v McAlister* [2009] NZSC 78, [2010] 1 NZLR 153 at [51], per Tipping J; and *Child Poverty Action Group v Attorney-General* [2008] NZHRRT 31 at [137].

discriminatory.[11] Once differential treatment on prohibited grounds is identified, the question of whether disadvantage arises is a factual determination.[12]

16. There is no case law in New Zealand on whether unlawful discrimination extends to differential treatment between individuals within the same ground (intra-ground discrimination).[13] However, we consider that intra-ground discrimination may be a ground of discrimination.

17. Further, we recognise that in the health and disability policy context, it is difficult to treat all people equally. Limited resources mean that difficult choices must regularly be made to prioritise funding of certain medicines over others, and that necessarily means that some people may not, for example, have access to a sufficiently wide range of funded medicines.

Does the Bill differentiate on a prohibited ground of discrimination?

18. Cancer is a large group of diseases that relate to the growth of abnormal cells in parts of the body.[14] Consistent with a broad and purposive interpretation of the term 'disability',[15] we consider that cancer is capable of being construed as a disability, given that its effects (including effects arising from treatment) can include physical impairment, physical illness, and loss or abnormality of physiological and anatomical function or structure.[16] We recognise that there can be a wide range of effects across cancer types and stages, and effects arising from treatment.

19. In our view, a possible group of people in an analogous or comparable situation (a comparator group) could be people with disabilities who need to have an unfunded medicine, that is not prescribed for cancer treatment, administered in a hospital setting. For example, this could be people with cystic fibrosis or inflammatory diseases such as Crohn's disease who are prescribed an unfunded medicine that requires hospital administration.

20. We recognise that constructing an appropriate comparator group in these circumstances is difficult. It is difficult to compare medical conditions in the abstract without having a particular condition or treatment in mind. We do not know the extent to which medicines are not funded for people with cancer and those in the comparator group, and why that is, for example, whether there an existing funded medicine that does not work for a particular patient. We also do not know the size and scope of both groups. Nor do we know whether hospital administration of those unfunded medicines is required for both groups.

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[11] *Ministry of Health v Atkinson*, above n 9, at [75].
[12] See for example, *Child Poverty Action Group v Attorney-General* [2008] NZHRRT 31 at [179]; and *McAlister v Air New Zealand* [2009] NZSC 78 at [40] per Elias CJ, Blanchard and Wilson JJ.
[13] However intra-ground discrimination has been considered before when assessing the proposed legislation's consistency with the Bill of Rights Act, see, for example, Hon Christopher Finlayson *Report of the Attorney-General under the New Zealand Bill of Rights Act 1990 on the Social Security Legislation Rewrite Bill* (8 March 2016).
[14] See World Health Organisation 'Cancer', accessible at: www.who.int/health-topics/cancer#tab=tab_1.
[15] The High Court has held that the definition of disability does not include the 'cause' of a disability (i.e. whether it is caused by an accident or illness), but the definition needs to be interpreted in a broad and purposive way: see *Trevethick v Ministry of Health* [2008] NZAR 454 (HC). The Convention on the Rights of Persons with Disability defines persons with disabilities as including 'those who have long-term physical, mental, intellectual or sensory impairments which, in interaction with various barriers, may hinder their full and effective participation in society on an equal basis with others'.
[16] We note that under the Equality Act 2010 (UK), a diagnosis of cancer meets the definition of disability under that Act (as a progressive condition), see UK Government 'Definition of disability under the Equality Act 2010', accessible at www.gov.uk/definition-of-disability-under-equality-act-2010.

21. However, to avoid taking an unduly technical approach to the comparator exercise, we consider that the Bill may treat those persons with disabilities other than cancer differently, based on whether they have been prescribed a medicine for cancer treatment which requires administration in a hospital setting.

Does the differential treatment have a discriminatory impact?

22. It is not stated in the Bill whether patients who require an unfunded cancer medicine to be administered in a hospital would or could be charged for those administration costs by a DHB. As the Bill prohibits the CFA from containing a term or condition that these patients cannot have their medicine administered in a hospital, the DHB could exercise its discretion on whether to charge a fee for the administration of a particular medicine in a particular case. However, given that the objective of the Bill is to share the cost of purchasing the unfunded cancer medicine and the cost of administering it between a cancer patient and the DHB, cancer patients may not be required to pay for the administration costs (either wholly or in part).

23. People in the comparator group are arguably prevented by the existing legislative framework from having their unfunded medicine administered in a public hospital, and that position would continue under the Bill because their unfunded medicine does not relate to cancer. They would continue to pay for both the unfunded medicine and any costs of administration in a private hospital.

24. While the cost of administering any unfunded medicine in a hospital setting, if required, will be highly variable depending on how the medicine needs to be administered and how frequently, we consider it could be presumed that these administration costs may be significant.[17]

25. On this basis, we consider that the Bill may materially disadvantage people who need to have an unfunded medicine that is not for cancer treatment administered in a hospital setting. These people may be put at a significantly higher expense than people who may have an unfunded cancer medicine administered in a public hospital presumably without charge or at a lesser expense.

Is the limitation justified under s 5 of the Bill of Rights?

26. Where a provision appears to limit a particular right or freedom, it may nevertheless be consistent with the Bill of Rights Act if it can be considered a reasonable limit that is demonstrably justified in a free and democratic society under s 5 of the Bill of Rights Act. The s 5 inquiry may be approached as follows:[18]

    a. does the provision serve an objective sufficiently important to justify some limitation of the right or freedom;

    b. if so, then:

        i. is the limit rationally connected with the objective?

[17] Costs may include clinic bed cost, nursing time, physician time, diagnostic tests required prior to infusion, materials required to deliver an infusion, time to prepare the infusion, set-up of the infusion, administration of the treatment, post-infusion monitoring, based on Pharmac 'Cost Resource Manual' (21 January 2020), accessible at: https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/economic-analysis/cost-resource-manual/#s4.

[18] *Hansen v R* [2007] NZSC 7, [2007] 3 NZLR 1 (SC).

ii. does the limit impair the right or freedom no more than is reasonably necessary for sufficient achievement of the objective?

iii. is the limit in due proportion to the importance of the objective?

Is the objective sufficiently important?

27. According to the New Zealand Cancer Action Plan 2019 – 2029, cancer is the leading cause of death in New Zealand.[19] In 2018, the leading causes of death in New Zealand were cancer, heart disease and brain disease - 114.0, 48.0 and 23.1 deaths per 100,000 population, respectively.[20] In 2016, 24,086 people were diagnosed with cancer, and this number is predicted to double by 2040.[21]

28. The Bill's stated policy objective is to improve access to public medical care for cancer patients who purchase unfunded cancer medicines that also require medical administration. Because of the high mortality rate for cancer, we consider that this appears to be a sufficiently important objective to justify some limitation on rights, but note that we do not know how many people in New Zealand have been (or need to be) prescribed unfunded cancer medication that requires hospital administration.[22]

Is there a rational connection between the limit and the objective?

29. Reducing the financial burden on people who have purchased an unfunded cancer medicine that needs administration in a hospital appears to be rationally connected to the objective of improving access to public medical care for people with cancer (in respect of the administration costs of that unfunded cancer medicine).

Is the impairment of the right no greater than reasonably necessary and in due proportion to the importance of the objective?

30. The Bill's Explanatory note states that it takes a principled approach to the distribution of scarce health resources by focusing on the most vulnerable cancer patients first, in the same targeted manner that other health resources are distributed, towards an overall goal of complete coverage for all.

31. Parliament is entitled to appropriate latitude to achieve its objectives.[23] Determining how to prioritise or allocate health resources is an area where we consider Parliament may be afforded such latitude. More generally, we consider that public health funding

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[19] Ministry of Health 'New Zealand Cancer Action Plan 2019 – 2029' (January 2020), accessible at: www.health.govt.nz/publication/new-zealand-cancer-action-plan-2019-2029, at 4.
[20] Ministry of Health 'Mortality web tool' (30 June 2021), accessible at: www.health.govt.nz/publication/mortality-web-tool
[21] New Zealand Cancer Action Plan 2019 – 2029, above n 21, at 4.
[22] We note that research commissioned by Pharmac in 2016 considered that while New Zealand funds fewer cancer medicines than Australia (there being 35 cancer medicines that Australia has funded that New Zealand has not, and 89 medicines funded in both countries), most of the additional medicines do not deliver clinically meaningful health gains in terms of extending time to disease progression or death for cancer patients: see Evans and other "Mind the gap: An analysis of forgone health gains from unfunded cancer medicines in New Zealand" Seminars in Oncology 43 (2016) 625 - 637, accessible at https://pharmac.govt.nz/news-and-resources/research/mind-the-gap-an-analysis-of-cancer-medicines-in-new-zealand-and-australia/. In 2019/20, Pharmac funded 14 new medicines (6 of which were cancer medicines) and widened access to 32 other medicines, estimating 71, 245 people benefited from these funding decisions (see Pharmac 'Mythbusting Pharmac' (17 March 2021), accessible at: https://pharmac.govt.nz/about/what-we-do/how-pharmac-works/mythbusting-pharmac/). According to Pharmac, new cancer medicines are constantly being developed, which often come with a significant cost and limited evidence of effectiveness, which can make it challenging for Pharmac to make funding decisions (see Pharmac 'Briefing to the Incoming Minister of Health' (9 November 2020) at 9).
[23] *Hansen*, above n 18, at [126], per Tipping J.

decisions necessarily distinguish between different health needs and conditions, similar to the social welfare context. Funding decisions regularly prioritise government assistance to those in need because of scarcity of resource. Such decisions will likely be justifiable in terms of the Bill of Rights Act, including where they are based on a clinical assessment of need/benefit, and are made after weighing and assessing standard criteria.

32. In the absence of the information we've identified above (see paragraph 20), but based on the high mortality rate for cancer, we consider that there may be a strong needs-based justification for providing additional financial assistance to cancer patients in the circumstances outlined in the Bill.

33. It is arguable that the Bill proposes a limited measure by relieving the costs of having an unfunded cancer medicine administered, not the actual cost of the medicine itself, such that the Bill may not impair the rights of other persons with disabilities who require an unfunded medicine to be administered in a hospital greater than is *reasonably* necessary (our emphasis).

34. We note that Pharmac already has a discretion under the NZPHD Act to provide funding in exceptional circumstances where medicine is not available on the schedule. For the most part, these exceptions do not distinguish between conditions. Creating a further exception for cancer patients in the circumstances outlined in the Bill, where the funding system already has a number of exceptions, may not be a disproportionate response where there appears to be a relatively strong needs-based justification for cancer patients.

35. Finally, we take into account that the effect of the Bill appears to enable DHBs to administer unfunded cancer medicines. We presume that decisions about the clinical benefits of doing so and the resources involved would be considered by a DHB faced with a particular request to administer an unfunded cancer medicine.

36. Overall, we consider that the measure proposed in the Bill could be reasonably open to Parliament to take in this health policy context as, on its face, the Bill's objective appears rational. For these reasons, we consider that any limitation on the right to be free from discrimination appears to be justifiable under s 5 of the Bill of Rights Act.

Conclusion

37. We have concluded that the Bill appears to be consistent with the right to freedom from discrimination affirmed in the Bill of Rights Act.

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