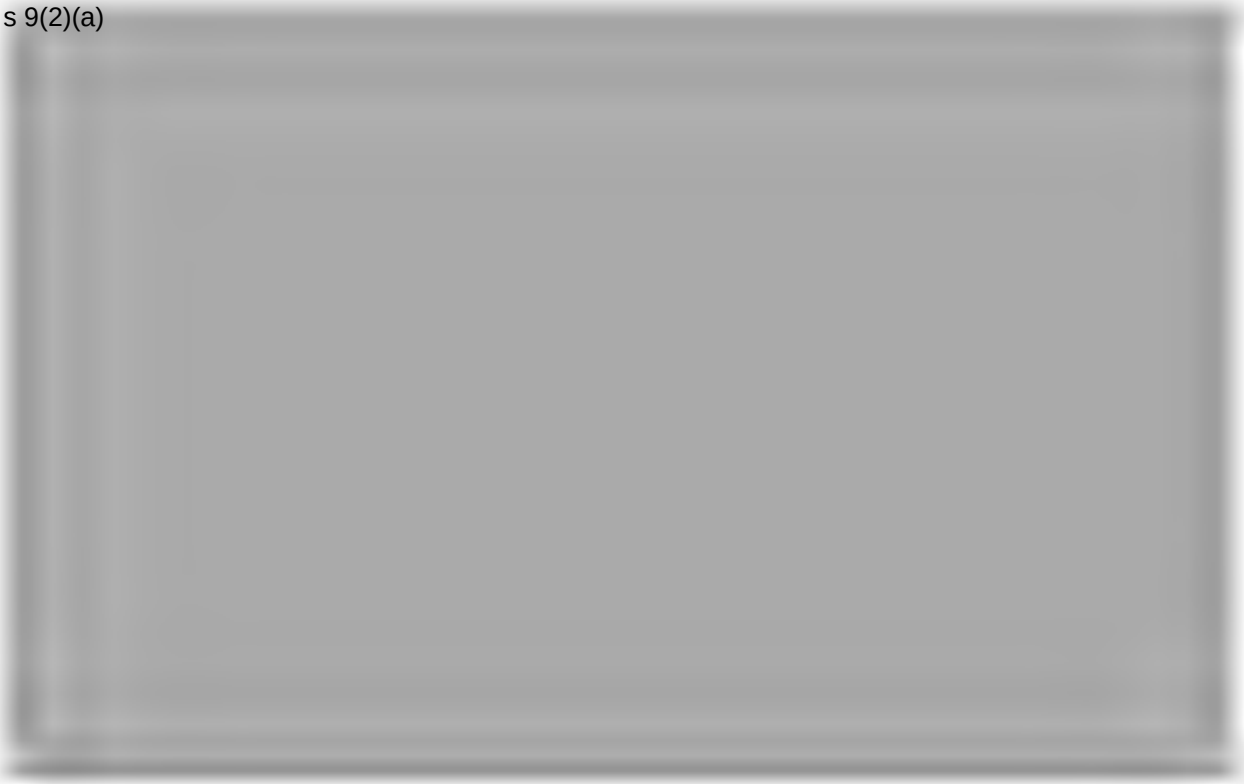
Appendix Five

Summary of the Technical and Consumer Procurement Evaluation Committee Meeting

Attendance

Present

s 9(2)(a)



Present from Pharmac
Adrienne Martin – Manager Pharmaceutical Funding (Day 2 only)
Conal Edwards – Therapeutic Group Manager (Day 1 and Day 2)
Josh Cronin-Lampe – Therapeutic Group Manager (Day 1 and Day 2)
Melissa Copland Senior Clinical Practitioner – Medical Advisory (Day 1 and Day 2)
Michael Chung – Procurement Manager (Day 1 and Day 2)
Robyn Harris (Day 2 only) - Senior Advisor Access Equity
Trevor Simpson – Director Māori (Day 2 only)

Background

1. Establishment and role of the Committee

In August 2023 Pharmac made the decision to establish an ad-hoc Technical and Consumer Evaluation Committee to assist with the evaluation of proposals we receive for the insulin pump and CGM RFP. This followed advice from the Diabetes Advisory Committee that specialist and consumer expertise would be required to evaluate the performance and suitability of different diabetes technologies.

Members were nominated by the New Zealand Society for the Study of Diabetes (NZSSD), Diabetes NZ, or selected from the Diabetes Advisory Committee or PTAC. The Committee also included a representative from the Data and Digital team at Te Whatu Ora.

All external advisors were subject to confidentiality agreements.

2. Interests declared

All external advisors have had their declarable interests reviewed by the Pharmac Legal Team. While the Pharmac Legal Team noted some perceived conflicts of interest, it was considered that no further action or management of these perceived conflicts was required as the Committee are acting in an advisory capacity and are not making final recommendations.

Pharmac's Legal Team have also carried out a check of Pharmac's staff interests register and found no apparent conflicts.

3. Role of the Committee

The role of the Committee was to:

- provide advice regarding the suitability aspects of insulin pumps (and consumables), CGMs and any associated software; the impact that particular features may have on patient use; and any technical or clinical rationale for excluding any particular products from further considerations and/or for selecting particular products in preference to others;
- assist Pharmac staff with ensuring that products are fit for purpose and meet the needs of patients; and
- provide advice regarding education and implementation considerations relevant to the supplier's proposals.

The Committee's advice was limited to the non-pricing aspects of the proposals we received.

4. Meeting Structure

The Technical and Consumer Evaluation Committee was held over two days, with overlapping membership. The Committee was split into two sessions, one focussing on the technical and clinical aspects of the proposals, and the other based on the suitability and implementation aspect. The sessions consisted of smaller group-based activities and Committee-wide discussion.

5. Purpose of the Summary

This paper provides a summary of the advice we received from the Technical and Consumer Evaluation Committee. The purpose of this summary is to inform the Pharmac Evaluation Committee in its evaluation of the proposals received, against Pharmac's decision making framework – the Factors for Consideration.

Continuous Glucose Monitoring (CGM) devices

This section summarises the advice we received from the Committee relating to the proposals for standalone CGM devices. We have organised the feedback under Pharmac's Factors for Consideration, principally the health benefit and suitability quadrants.

6. General comments on CGM devices

The Committee noted that three of the devices had been reviewed and recommended for funding by the Diabetes Advisory Committee (Freestyle Libre, Medtronic Guardian, and Dexcom G6 CGMs). The Committee considered that there is more experience with these products in the New Zealand Health System and that the clinical evidence supporting these products is more mature. The Committee considered that this is not reason to preclude the other options from further evaluation but considered that the accuracy of newer products should undergo more rigorous assessment if Pharmac was to consider funding these.

Health benefit

The Committee noted a review article by Heinemann et al. (2019), where the authors outline that the mean absolute relative difference (MARD) parameter has significant limitations as a surrogate market for real-world accuracy and should not be the sole parameter to determine the performance of CGM devices (Heinemann. L et al., 2020. Benefits and Limitations of MARD as a Performance Parameter for Continuous Glucose Monitoring in the Interstitial Space. *J Diabetes Sci Technol*. 2020 Jan;14(1):135-150. doi: 10.1177/1932296819855670.). The Committee considered that the (MARD) provided by suppliers may differ in the real-world setting for several reasons. The Committee noted that many of the proposals received do not include the error grid analysis required for a comprehensive assessment of accuracy across the glucose range.

The Committee noted a review article by Pemberton et al. (2022) which compares the performance of different CGM devices available in the United Kingdom against the FDA's integrated CGM (iCGM criteria) (Pemberton et al., 2022. CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA): A narrative review. *Diabetes, Obesity, and Metabolism.* April; 25(4):916-939 https://doi.org/10.1111/dom.14962). The Committee noted that the observed accuracy of the CGM devices in the hypoglycaemic range is a concern

compared with the reported MARD figures. The Committee considered there was stronger evidence to support the non-adjunctive use of the Freestyle Libre 2 and Dexcom G6 CGMs, and that the Dexcom G6 performed particularly well in the hypoglycaemic range.

The Committee considered a shorter sensor warm-up period to be a significant advantage for all users, but especially for people using an automated insulin delivery (AID) system. The Committee noted that no data is generated during the warm-up period resulting in a period in which patients would have a gap in their glucose readings.

The Committee also considered that the system performance of an AID combination should be considered quite separately from the performance of the component CGM.

Suitability

The Committee considered the requirement of CGMs for finger-prick calibration to be a significant barrier to the use of CGMs. The Committee considered that any CGM device requiring finger-prick calibration should not be considered for further evaluation.

The Committee considered that at least one standalone reader device should be available, as not all people using CGMs would have access to a compatible smartphone. The Committee noted that while the lists of compatible smartphones is constantly being updated by suppliers, even some newer models of smartphones are not compatible.

The Committee estimated that approximately 25% of all people using CGMs would require a standalone reader device. The Committee considered the following groups of people who would need a standalone reader device would include:

- Children, especially those who are not permitted to carry phones with them at school.
- People who do not have personal phones (e.g. people who use a communal family phone or people who use work phones).
- People who are unable to carry their phones with them due to their job or personal circumstances.

The Committee also considered that some people would want access to a standalone reader as a backup to their smartphone. The Committee noted that CGMs are connected to smartphones via Bluetooth which may reduce phone battery life and so a backup reader device would be useful if a phone were to run out of battery.

The Committee noted that while there is no formal regulatory approval process for medical devices in New Zealand, many CGMs have undergone the regulatory approval process in other jurisdictions such as Australia, the United States and Europe. The Committee noted that many products are only indicated for use from a minimum age. The Committee considered that there would potentially be some off-label use of devices outside the manufacturer's licenced populations and noted that this may potentially result in the voiding of product warranties. The Committee

considered it important that Pharmac staff confirm with suppliers if this would be the case.

The Committee considered a combined all-in-one sensor with transmitter device to be advantageous. The Committee noted that some transmitter devices that are separate components are quite small and can be easily lost and are problematic for changing requiring a high degree of manual dexterity.

The Committee considered a longer sensor wear-time to be advantageous. However, the Committee also noted that in practice some sensors do not last as long as their advertised life and that this may have financial implications for Pharmac if patients are having to replace their sensors more frequently than their advertised life. The Committee highlighted that it would be important for Pharmac to consider how people would access replacement products if the devices are lost, faulty or damaged. The Committee noted that suppliers in the private market are currently responsible for replacing products and that it should remain the responsibility of suppliers if these products are publicly funded.

The Committee noted that children who are initiated on CGMs at a young age may experience scarring at the insertion site and that this extensive scarring may result in the shortening of sensor life.

The Committee noted that individuals have different sensitivities to different adhesives, tapes and over patches. The Committee considered it important for people to be able to switch between funded CGMs if they experience reactions to the funded adhesives of one brand.

The Committee noted that in practice, some people supplement the adhesives, tapes or overpatches included with a CGM device with additional adhesive to help secure the sensor more securely and to support full sensor life. The Committee considered there could be equity implications for people unable to afford or access additional adhesives.

The Committee considered that it would be important for Pharmac to think carefully about any restrictions on the maximum number of sensors allowed in a certain period.

7. Abbott Freestyle Libre 2 and Libre 2+

The Committee noted that Abbott submitted proposals for both the Freestyle Libre 2 and Freestyle Libre 2+. The Committee noted that the Libre 2 would be launched initially before being superseded by the Libre 2+ during the dual-supply period, provisionally in the first quarter of 2025. The Committee noted that the Libre 2 and Libre 2+ are identical except the Libre 2+ has a lower MARD, a longer sensor-life and will have AID system functionality.

Health benefit

The Committee noted the recent update to the Freestyle Libre 2 in September 2023 resulting in the Freestyle Libre 2 now sending glucose readings automatically every minute to a connected smartphone or reader device without the need for intermittent

scanning. The Committee considered that this was a significant step forward in terms of functionality.

The Committee noted that the per minute reading frequency of the Freestyle Libre 2 is more frequent than other devices and considered that this would be especially useful when glucose levels are rapidly changing.

The Committee noted that the Abbott Freestyle Libre 1 was given a high priority recommendation for funding by the (then) Diabetes Subcommittee in 2019 and considered that there is strong clinical evidence to support the health benefits associated with its use.

The Committee considered that the available evidence demonstrates that the Freestyle Libre 2 demonstrated good accuracy in both adults and children. The Committee noted that in a cross-product analysis (Pemberton et al., 2022) it performed slightly worse than the Dexcom G6 CGM across the full glucose range. The Committee considered that in most situations, this difference was not clinically significant, but that the greater inaccuracy of the Freestyle Libre 2 in the hypoglycaemic range could be clinically significant in some situations. The Committee noted that the Freestyle Libre 2 sensors are one of two CGMs to have been FDA approved as iCGM for use in AID systems.

The Committee noted that finger-prick calibration is not required with the Freestyle Libre 2.

The Committee noted that a standalone reader device is available for the Freestyle Libre 2.

Suitability

The Committee noted that the Freestyle Libre 2 has a water resistance rating of IP27[1]. Some Members considered this may be an issue for people who swim regularly and who may spend longer than 30 minutes in water. However, the Committee did not consider this to be a reason for the Freestyle Libre 2 to be excluded from further evaluation.

The Committee considered the Freestyle Libre 2 to be easy to insert. However, some Members noted that when the Freestyle Libre 2 has been inserted, there is a lip between the skin and the sensor which can get caught on clothing or doorways resulting in the sensor being detached. The Committee did not consider this to be a reason for the Freestyle Libre 2 to be excluded from further evaluation.

The Committee considered the Freestyle Libre 2 and associated software to be easy to use, intuitive and user-friendly making it a good choice for people newly diagnosed with diabetes.

s 9(2)(b)(ii)

[redacted]

[1] Immersion in water to up to 1 metre for 30 minutes

s 9(2)(b)(ii)

9. NZMS – Dexcom CGMs

The Committee noted that NZMS submitted proposals for both the Dexcom G6 and Dexcom One CGMs. The Committee noted that the hardware of the Dexcom One and G6 are similar and that these products differ mainly in their functionality.

The Committee also noted that NZMS indicated it could also potentially roll out the Dexcom G7 and Dexcom One+ during the dual supply period. The Committee noted

that the G7 and One+ are the corresponding next-generation devices of the G6 and One respectively.

Dexcom G6

Health benefit

The Committee noted that there was strong evidence supporting the accuracy of the Dexcom G6 across the full glycaemic range in both adults and children.

The Committee noted that a standalone reader device is available for the Dexcom G6.

The Committee noted that hydroxyurea may falsely elevate glucose readings from the Dexcom G6.

The Committee noted that finger-prick calibration with is not required with the Dexcom G6 but that optional finger-prick calibration is possible which some people may find beneficial.

Suitability

The Committee noted that the Dexcom G6 sensor has a range of approved insertion sites (abdomen, back of arm, and upper buttocks). The Committee considered this advantageous over products with fewer approved insertion sites.

The Committee considered that the separate transmitter was a suitability disadvantage as these can be lost.

Dexcom One

Health benefit

Unlike the Dexcom G6, the Dexcom One does not have AID functionality. The Committee also noted that unlike the Dexcom G6, the Dexcom One does not have “urgent low soon” alert functionality and does not allow for approved caregivers to follow data via the Dexcom Follow app.

The Committee considered that the “urgent low soon” alert functionality is critical for people who can’t communicate, those who are hypoglycaemic unaware, or who are at risk of severe hypoglycaemic events.

The Committee considered the Dexcom One would be an appropriate standalone CGM option for most people who would benefit from a CGM but who do not need the AID functionality. However, the Committee considered that the Dexcom G6 would be a more appropriate option than the Dexcom One for some people on MDI regimens due to the additional functionality.

The Committee noted that like the Dexcom G6, the Dexcom One is also affected by the hydroxyurea interaction.

The Committee noted that a standalone reader device is not available for the Dexcom One.

Dexcom G7

Health benefit

The Committee considered that the G7 had strong evidence of accuracy across the fully glycaemic range.

The Committee noted that the G7 is currently available in New Zealand but that it currently does not have AID system functionality. The Committee noted that NZMS has indicated that AID system functionality is expected to be available during the dual supply period.

The Committee noted that like the Dexcom G6 and Dexcom One, the G7 is also affected by the hydroxyurea interaction.

Suitability

The Committee noted that the G7 is a combined all-in-one sensor with transmitter device.

Dexcom One+

Health benefit

The Committee noted that like the Dexcom One, the One+ will not have AID system or “Urgent Low Soon” alert functionality. However, unlike the Dexcom One, the One + will have “Follow” functionality.

The Committee noted that from the information provided, it was unclear as to whether the Dexcom One+ would also be affected by the hydroxyurea interaction.

The Committee noted that a standalone reader device would be available for the Dexcom One+.

Suitability

The Committee noted that the Dexcom One+ is a combined all-in-one sensor with transmitter device.

s 9(2)(b)(ii)

s 9(2)(b)(ii)

s 9(2)(b)(ii) [redacted]

Table 1. Summary of advantages and disadvantages of standalone CGM proposals noted by the Committee.

Supplier proposal	Advantages	Disadvantages
Abbott (Freestyle Libre 2)	• No finger prick testing required for calibration or readings • Sensor lasts for 14 days • Health system familiarity • Easy to apply and simple to use • All in one sensor device • Small and discreet sensor • Optional real-time alarms for low and high glucose levels • Now sends through information in real-time • Separate reader device for those who need it • Shorter warm up time	• Integration with insulin pumps not due for some time • No predictive alerts for glucose trends • Not as accurate as some other CGMs in the hypoglycaemic range
s 9(2)(b)(ii)		

Supplier proposal	Advantages	Disadvantages
Dexcom (G6, G7, One, One+)	• No finger prick testing required for calibration or readings • Broad range of customisable alarms including rapid change alarms • Health system is familiar with the products • Separate reader device • Better water immersion rating than other products • Wide range of approved sites • Easy to apply • Accuracy in hypoglycaemic range • Compatibility with multiple devices • G7 and One+ all in one sensor devices	• G6 CGM has a separate transmitter device, which can be lost • Shorter wear time than some other CGM options • Larger and more noticeable sensor • Transmitter needs to be replaced every 90 days
s 9(2)(b)(ii)		

Insulin pumps and automated insulin delivery (AID) systems

12. General comments

Health benefit

The Committee acknowledged the significant cognitive load required to manage diabetes. The Committee considered that AID systems not only provide a direct clinical glycaemic benefit for people with diabetes but other indirect benefits including improved quality of sleep and improved productivity due to the reduction in mental energy required for diabetes management.

The Committee noted that the AID systems use different algorithmic approaches to calibrate insulin delivery to the user's blood glucose. The Committee noted consensus recommendations for the use of AID systems, which included a summary of each AID system, the algorithmic approaches used to calibrate to insulin delivery, and the supporting clinical evidence (Phillip. et al. *Automated Insulin Delivery Technologies in Clinical Practice*, Endocrine Reviews, Volume 44, Issue 2, April 2023, Pages 254–280, https://doi.org/10.1210/endrev/bnac022).

The Committee also noted a systematic review of AID systems (Peacock et al. "A Systematic Review of Commercial Hybrid Closed-Loop Automated Insulin Delivery Systems." *Diabetes therapy : research, treatment and education of diabetes and related disorders* vol. 14,5 (2023): 839-855. doi:10.1007/s13300-023-01394-5)

The Committee considered that the available evidence demonstrates that all the AID systems under consideration provide significant benefits above both CGM plus MDI and sensor augmented pump therapy. While the Committee noted that the reported outcomes (e.g. time in range, HbA1c, reduction in hypoglycaemic events) across trials are quite similar, there have been no head-to-head trials of the various AID systems. As such, the Committee considered that it is difficult to make any general conclusions about comparative performance. The Committee noted that anecdotally certain patient subgroups can benefit more from some AID systems compared with others, hence why some choice is important for patients and clinicians alike.

The Committee noted that funding is currently restricted to one insulin pump per patient per 4 years as a measure to contain costs. The Committee noted there is currently no option for patients to trial different pumps to determine which is the most appropriate for their needs. In lieu of a trial the Committee considered it was especially important that patients and clinicians receive adequate training and support. The Committee also noted that when patients are provided with an insulin pump to replace a faulty in-warranty pump, the warranty period is not renewed with the replacement pump. Therefore, patients would require a new pump following the expiry of the original warranty despite the replacement pump being relatively new. The Committee considered this to be an unnecessary cost to Pharmac and that it causes unnecessary stress and anxiety for patients.

s 9(2)(b)(ii) [redacted]

s 9(2)(b)(ii) [redacted]

The Committee noted that only the CamAPS FX algorithm is currently indicated for use in pregnancy. The Committee highlighted that women planning pregnancy who are using other algorithms would either need to change insulin pumps, CGM and/or algorithm once pregnant or to use an algorithm off-label. The Committee noted that glycaemic control is important both preconception and during pregnancy and considered it preferable that women are maintained on the same AID system preconception, during pregnancy and post-partum.

The Committee noted that the CamAPS FX algorithm is indicated for use in children aged 1 year and above. The Committee noted that this is the lowest minimum age of all the algorithms proposals were received for. The Committee noted that while other algorithms may not be indicated for use in this age group, there is already some off-label use in these people. The Committee noted that trials investigating the use of other AID systems in younger children were underway.

The Committee considered the relative advantages and disadvantages of insulin pumps with rechargeable batteries versus replaceable batteries. The Committee noted that some people are anxious about using rechargeable batteries in the event of a power outage. However, the Committee also considered that using replaceable batteries may have equity implications as some households may not be able to afford to buy batteries regularly.

s 9(2)(b)(ii) [redacted]

The Committee noted that some insulin pumps can be controlled via a smartphone app while others must be operated through the insulin pump itself. The Committee considered that the ability to operate an insulin pump remotely via a smartphone or other device may reduce some of the stigma associated with using an insulin pump as the pump could be controlled discreetly without the need for users to reveal it in public. The Committee also considered this beneficial as caregivers would be able to deliver bolus doses remotely.

s 9(2)(b)(ii) [redacted]

s 9(2)(b)(ii)

15. NZMS - Tandem t:slim X2 with Control-IQ

Health benefit

The Committee noted that the Tandem t:slim x2 insulin pump is currently listed on the Pharmaceutical Schedule and that most diabetes clinicians would be familiar with its use.

The Committee noted that the Tandem t:slim x2 pump has the highest minimum basal rate at 0.1 units per hour. The Committee considered this would be an issue for a small number of patients who require very low rates of basal insulin, however, there are workarounds that clinicians use.

The Committee noted that the Control-IQ algorithm uses a treat to range adaptive model. s 9(2)(b)(ii)

The Committee noted that the Control-IQ algorithm does not automatically deliver bolus doses for meals. The Committee considered the Control-IQ algorithm is most effective in people who regularly deliver a bolus insulin dose before meals.

Overall, the Committee considered the Tandem t:slim x2 pump (with Control-IQ) to be an effective AID system for most people and that the algorithmparticularly effective at managing overnight glucose levels.

The Committee noted that the Control-IQ algorithm is not indicated for use in pregnancy or in children under 6 years old.

Suitability

The Committee noted that the Tandem t:slim x2 insulin pump cannot be controlled via a smartphone and that it must be operated by controlling the insulin pump itself.

The Committee noted that the Tandem t:slim x2 pump uses a touch-screen interface and a rechargeable battery. The Committee considered the touch-screen interface easy to use but also considered that some people may find the small text size hard to read. The Committee considered the smaller size of the T:slim x2 insulin pump to be an advantage.

The Committee considered that due to the requirement to deliver bolus doses, the Control-IQ algorithm would be particularly suitable for people who want to adopt a more "hands-on" approach to managing their diabetes.

16. Pharmaco - Ypsopump with CamAPS FX algorithm

Health benefit

The Committee noted that the CamAPS FX algorithm is indicated for use in pregnancy and in children from the age of 1 year old and considered this to be a significant advantage.

The Committee noted that the CamAPS FX algorithm uses an adaptive approach to algorithmic learning. The Committee noted that over time the model adapts to calibrate insulin doses to the user's prandial and diurnal patterns. The Committee noted that this adaptive approach occurs independently of programmed basal and sensitivity pump settings. The Committee considered that correction boluses are not required as the algorithm is constantly learning and adapting.

Suitability

The Committee noted that the CamAPS FX algorithm requires a smartphone to operate and is currently only compatible with Android, noting that iOS compatibility is expected in mid-2024. The Committee considered there would be equity implications if a smartphone is required to operate the algorithm.

The Committee considered the ability of the Ypsopump infusion set consumables to be inserted in any orientation to be advantageous.

The Committee noted that the Ypsopump glass reservoir only has a capacity of 160 units and that this is smaller than the other insulin pumps. However, the Committee noted that glass reservoirs can be pre-filled with insulin and stored in the fridge unlike plastic reservoirs.

The Committee noted that the Ypsopump can be controlled remotely via smartphone but that it can also be controlled directly through the pump. However, the CamAPS FX algorithm requires an Android smartphone.

The Committee noted that the Ypsopump is smaller and lighter than either of the currently funded pumps and considered this to be advantageous.

The Committee noted that the Ypsopump has a touch screen interface and uses replaceable batteries. The Committee noted that the Ypsopump menus are icon-based with minimal text and considered this could be advantageous for people with reading difficulties.

s 9(2)(b)(ii)

s 9(2)(b)(ii)

Broader implementation considerations

The Committee considered the quality of the initial training and onboarding process for AID systems to be crucial for patients to derive the most benefit from AID systems. The Committee considered that patients who undergo a high-quality onboarding process are more likely to feel empowered to use their AID system effectively and require less follow up. The Committee noted that onboarding processes and other wraparound support differs significantly across regions and that this needed to be standardised across all regions.

The Committee considered it important for suppliers to provide as much onboarding and education as possible noting the current resourcing constraints across the health sector. The Committee noted in particular the patient benefit of high-quality instructional videos. It was noted that programs such as group training are also extremely valuable.

The Committee considered there would likely be significant demand for both AID systems and CGMs as soon as they are listed on the Pharmaceutical Schedule and that there would be an initial bolus of patients who are currently funding these systems privately who would attempt to access public funding. The Committee considered it important for Pharmac to manage public expectations regarding the timeframes for being able to access these technologies (particularly AID systems) given the significant resourcing constraints in the health sector. However, the Committee acknowledged that people currently accessing diabetes technologies privately would already be familiar with the use of the products and that minimal additional training would be required for these people. The Committee also considered it important that the health system prioritises those at high risk who would gain the greatest health benefit from these technologies given the current resourcing constraints.

The Committee considered that while insulin pump and AID system onboarding would still need to be completed in secondary care, the onboarding of CGMs could be carried out in primary care. The Committee considered that upskilling and utilising health coaches and other kaiawhina who have undergone appropriate training could take some of the pressure off GPs, nurses and other clinicians within primary care.

The Committee acknowledged that Pharmac is not solely responsible for the implementation of this decision and that successful roll-out will require significant collaboration and engagement with partner agencies and organisations across the broader health sector. The Committee considered it important for suppliers to dedicate significant resource to education and onboarding programmes for insulin pumps and AID systems given health sector constraints.

The Committee noted the current insulin pump market split of approximately 65/35 with the currently listed Tandem and Minimed insulin pumps respectively. The Committee noted that these are aggregated national figures and that the market split may be different across different regions with some regions favouring the Tandem pump or vice versa. The Committee highlighted that the impact of a brand change in insulin pumps may therefore differ across regions.

The Committee noted that there had been several insulin pump transitions in the past (Animas to Tandem, and Minimed 640G to Minimed 770G). However, in these situations, the same supplier was transitioning patients from one of their own pumps to another pump they supplied so were invested in supporting a smooth transition. If this

RFP were to result in a change in funded insulin pumps then the incoming and outgoing insulin pumps would be supplied by different suppliers which may result in a more challenging transition as the outgoing supplier would have less incentive to support a smooth transition.

Data and Digital

The Committee considered that all proposals received lacked sufficient detail about their data management and data sovereignty policies to comment on their appropriateness for the New Zealand context.

The Committee highlighted that while several suppliers referenced international standards, no suppliers referenced the New Zealand Information Security Manual (NZISM) which outlines the minimum requirements for protecting New Zealand Government information and systems. The Committee noted that as a member of Five Eyes, any data infrastructure would need to be consistent with data infrastructure requirements across the public sector.

The Committee acknowledged the challenges of obtaining informed consent from users regarding the use of their data. The Committee noted that many suppliers of software and apps sell de-identified user data to overseas-based third-parties. The Committee recognised that patients would likely not be able to use the relevant software (including AID algorithms) unless they consented to their data being shared as per the supplier's privacy policy. Therefore, users would need to balance whether they were comfortable with their data being shared versus whether they want to gain the benefits from using the software. However, the Committee acknowledged that many users already consent to their data being shared with third-parties in a similar manner through other commonly used software or apps including social media or Google. The Committee considered that suppliers would need to provide clear education to patients about what their data would be used for during the onboarding process.

The Committee expressed concern about the lack of information relating to data sovereignty or the strength of their data encryption practices. The Committee acknowledged that there are very few if any data servers based in New Zealand and that any data generated through diabetes technologies would be sent and stored overseas raising issues over who owns the data and under which jurisdiction's laws and regulations the data would be subject to. However, the Committee acknowledged that major data server providers such as Azure and AWS have indicated they are planning to open servers in New Zealand in the future. The Committee considered that Pharmac could request that any data generated through funded diabetes technology be stored in Australian based servers until the New Zealand based servers are operational.