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29th September 2021

Mr Darrell Channing
Director – Competition Exemptions
ACCC

Email: exemptions@accc.gov.au

Dear Mr Channing

PEN CS Response AA1000577 - WAPHA - SUBMISSION

We strongly oppose the application for interim authorisation and authorisation.

Summary

- 1. The Applicant has not demonstrated urgency.
- There is no unmet public benefit that would be satisfied by the grant of an interim authorisation.
- The Application to the ACCC by the Applicant is conduct which is likely to be found to be not in accordance with Commonwealth Guidelines applicable to Primary Health Network managers. The ACCC should not support that conduct.
- There are serious unresolved privacy and commercialisation issues in connection with the Applicant's proposal.
- There are serious unresolved access and interoperability issues in connection with the Applicant's proposal.
- 6. The Applicant has not disclosed relevant material to the ACCC.
- 7. There has been a lack of appropriate notification (caused by the Applicant).
- 8. The proposed conduct is exclusionary.
- 9. General the ACCC should not support poor outcomes

No Urgency

- 1.1 The terms of the interim authorisation sought by the Applicant are set out at 2.4.1 of the Application.
- 1.2 It is noted that whilst the Applicant states at 2.4.1(a) that interim authorisation is sought to enable the development phase under Contract A to take place, in fact the Applicant wishes to undertake all the relevant preparation conduct under proposed Contract B during this period. This is made plain at 2.4.1(c) where the Applicant states that during this interim period it will "plan and commence the transition of some of the Participating PHNs to Primary Sense 2".

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- 1.3 The Applicant is therefore, in substance, seeking to confirm and sign up a portion of its customer base (the Participating PHNs) early so as to lock them in to contact prior to the Applicant in fact committing its development funds under Contract A to create Primary Sense 2.
- 1.4 Evidently the only purpose behind the request for an Interim Authorisation is the commercial imperative to sign up "some of the Participating PHNs" prior to those organisations being required to make a decision whether to renew their existing data extraction licences. That is not a proper foundation for the ACCC to grant Interim Authorisation.
- 1.5 The Primary Sense 2 data extraction software does not presently exist. It may never exist, or it may come to exist in a form which is not fit for purpose.
- 1.6 All PHNs currently fulfil their duties and objectives utilising existing 3rd party data extraction tools. No submission or evidence has been placed before the ACCC by the Applicant that those existing arrangements are not fit for purpose, or somehow cause hardship to PHNs in carrying out their functions or are otherwise unsuitable.

No Unmet Public Benefit

- 2.1 There is significant public benefit derived from vibrant competition which allows innovation and market forces to drive demand.
- 2.2 The requested Interim Authorisation will prevent the natural supply/demand forces and is anti-competitive. It is also misaligned with PHNs commissioning Framework and Commonwealth guidelines.
- 2.3 If the proposed conduct is not authorised:
 - Contrary to [4.2.2] Participating PHNs will not incur higher costs. The Applicant has not
 provided any cost analysis. The cost analysis into ROI on existing packaged solutions would
 demonstrate favourable commercial terms.
 - Contrary to [4.2.3] Primary Sense is not better suited to PHNs. The product was released by Gold Coast PHN to market in 2019 and to this date has only 1 PHN using the platform.
 - Market forces are not indicating that Primary Sense is fit for purpose or 'better suited' as implied.
 - In response to [4.2.4] risk of commercialisation of Data should not be confused with Interoperability. Pen CS does not hold patient data at all. The data is held by each PHN.
 - Pen CS is focused on driving interoperability which it currently does across 13 different
 patient management computer systems in operation throughout Australia. Enabling GPs to
 use their data in new technology solutions, for example team care and medical devices for

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at home patient monitoring, is an evolution that will relieve burdens on the healthcare system if applied appropriately within agreed governance and consent frameworks. These future health innovations should not be confused with the concept of commercialisation of data.

2.3 There will be Public detriment.

Pen CS has invested years of research and development and huge amounts of financial commitment into building a platform that many PHNs now use daily. Given the Commonwealth imposed funding structures on PHNs, we have extremely lean margins on prices.

Pen CS would not be able to provide its existing platform at the current price if market share declined significantly due to exclusionary conduct. In fact, Pen CS would be at risk of severe commercial decline.

The Pen CS software model provides protection for the management of personal information as we do not store any patient data. There is a natural security layer between data collection, data aggregation and re-identification only at point of care.

If Primary Sense 2 is developed by Gold Coast PHN, using taxpayers' funds, and then further deployed within the PHI (itself the subject of ACCC Authorisation – CB10000468.1), using taxpayer funds, then it appears that PHNs are developing and selling software to themselves. This approach will significantly reduce competition and is detrimental to the public and to the Commonwealth's health purposes.

Commonwealth Guidelines

- 3.1 The Applicant has not addressed whether the purpose of the Participating PHNs [2.1.6] is compliant with the fundamental Objectives of PHNs [1.3].
- 3.2 The relevant question is whether PHNs are funded to develop software applications under the current legislation and program guidelines when existing applications are in market, fit for purpose, digitally proven to operate at scale and widely used.
- 3.3 Attached is a copy of the Department of Health's Guidelines for PHNs. The ACCC should investigate and assess whether the Guidelines permit PHNs to directly engage in support service development and operation in the context of the current market environment. It is submitted that these objectives do not include software development when existing solutions are readily available and in use from the private and not-for-profit sectors.
- 3.4 The Guidelines express that PHNs should not seek to duplicate efforts of other private or public sector entities [Guidelines 1.6.1].
- 3.5 The Guidelines express that PHNs are to achieve value for money as a core requirement of purchasing and commissioning, which amongst other matters, requires encouraging competitive and non-discriminatory procurement/purchasing processes and also to consider

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fitness for purpose. Innovation and adaptability and whole of life costs [Guidelines 1.6.1]. Here the Applicant has demonstrated none of these matters to the ACCC so as to warrant an authorisation to be immune from its proposal to engage in the proposed conduct.

- 3.6 The Commonwealth Government's 2018 Final Report on the Evaluation of the Primary Heath Networks Program stated [at 10] that some of the key defining characteristics of PHNs (on top of being independent, regional, and membership based organisations, are that PHNs do not directly provide services, except in the case of market failure.
- 3.7 The Applicant has not asserted any market failure. It would be ironic, and contrary to good public policy, for the ACCC to authorise the proposed conduct amongst entities that were set up by government to be independent, and in a particular market where there is no present market failure.

Privacy & Commercialisation Risks

- 4.1 There is limited to no visibility on the Data Governance Framework for the unincorporated PHI (the unincorporated joint venture) nor how PHI plans to prevent commercialisation or inappropriate use of the data. This aspect was noted in the Commonwealth Governments 2018 Final Report on the Evaluation of the Primary Heath Networks Program. [see pages 6 & 7 at Table 1 at the headings "Governance" and "Program guidance" and the in depth discussion at 4.2].
- 4.2 There is also significant lack of transparency around the PHI entity and its role with regards to responsible use of data. (By way of contrast, Pen CS does not hold data and is not a data custodian. This separation of roles and responsibilities creates an additional security layer for General Practices and Aboriginal Medical Services who are the data owners).
- 4.3 There is a serious question as to whether the establishment of an unincorporated joint venture is permitted by, or is consistent with, the very establishment of the Primary Health Network (which consists of 31 Independent and regionally based networks) to fulfill its core functions.

Access & Interoperability

- 5.1 The Application at [2.1.8] states that the IP in Primary Sense is assigned to participating PHNs as tenants in common in equal shares. What happens to the IP when PHNs dissolve or change?
- 5.2 In relation to data storage, it is understood than arising from the ACCC authorisation in 2019 to the Tasmanian Primary Health Network, that Microsoft Azure was the data storage platform selected and which is now in operation. The present Applicant has not provided to the ACCC any outcomes from that authorisation, and in particular:
 - has not provided evidence to show whether (or not) the authorisation then given did
 in fact lead to making it easier for PHN organisations to co-ordinate with other PHN
 organisations [ACCC assessment criteria at 18].

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- has not provided evidence to show whether (or not) the authorisation then given
 has led to the public benefit of improved co-ordination of data and communication
 between PHN organisations [ACCC public benefit criteria ay 19].
- has not provided evidence to show whether (or not) the authorisation then given has led to the public benefit of transaction cost savings [ACCC public benefit criteria at 19].
- d. has not provided evidence to show whether (or not) the authorisation then given has led to the public benefit of increased input into contracts with the ICT supplier to better reflect the needs of the PHN organisation [ACCC public benefit criteria ay 19].
- 5.3 No disclosure has been made to the ACCC by the Applicant as to which entity is recorded as the owner of the Microsoft Azure "Tenancy". (the owner of the "Tenancy" being the most important aspect of control and ownership of any data residing within that Microsoft platform).
- 5.4 The Applicant has not disclosed to the ACCC the arrangements (contractual and otherwise) intended to be implemented (if at all) to allow for interoperability of other software services to connect to and interact with the data to be controlled by the PHI.
- 5.5 The Applicant has not disclosed to the ACCC the arrangements (contractual and otherwise) intended to be implemented for the admission of PHNs (not already participating) into the unincorporated joint venture or the terms of exit and the consequences for access to data upon exit from the unincorporated joint venture.

Frankness

- 6.1 The Applicant has not updated the ACCC with outcomes from the prior authorisation it obtained in 2019.
- 6.2 The table at [2.1.3] is not extensive and omits other viable data collection platforms currently in use in Australia.

6.3

- 6.4 The Applicant has not disclosed to the ACCC that the underlying data analysis engine used in Primary Sense is the John Hopkins ACG. Nothing is disclosed to the ACCC about the origins of that engine, its suitability for the Australian context, or the local context in which each PHN organisation operates, the legal and commercial arrangements in place with john Hopkins or the cost structures which will be applicable.
- 6.5 The ACCC should note that Pen CS and Outcome Health do not use the John Hopkins ACG engine (because fundamentally it is not designed for the Australian context, and it is too expensive), but each have developed (in house) their own engine.
- 6.5 Why are PHNs developing software applications?

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- No Procurement Process: There is no transparency and lack of visibility over the PHI entity
 and how it came to select Primary Sense as a fit for purpose software application. There was
 no public procurement process which is misaligned with the required Commissioning
 Framework for PHNs.
- Lack of Information: There is lack of public information about why and how PHI was selecting a 'favoured' data collection tool when there are fit for purpose applications in market, currently widely in use and at competitive rates.
- Whole of Life costs: There is no analysis by the Applicant demonstrating value for money to each PHN to show a significant public benefit to go towards balancing the otherwise exclusionary conduct.

Notification

7.1 Lack of Notice to relevant parties.

The Application for Authorisation should have been circulated to other relevant groups including the Medical Software Industry Association of Australia.

The list of "Persons affected" at 2.6 of the Application is not complete. It is a simplistic view of those impacted and shows the lack of knowledge of the extent of market competitors, participants and genuine stakeholders.

Fundamentally the data being captured, parsed, analysed and reported upon is, in the main, generated and owned by individual GP Practices. Their views regarding the above topics of privacy, governance, access and commercialisation risks into the future have not been sought, but should be.

7.2 Lack of Time to Respond.

Pen CS was given less than 5 working days to respond. It has subsequently been granted a 48 hour extension. This is unreasonable in the current environment with vaccine rollout, high demand on medtech companies and the length and opaqueness of the WAPHA submission.

Exclusion

- 8.1 The Applicant at [2.2.1] does not mention which features of the PHN structure are being referenced or are relevant. The same can be said for the reference to the Commonwealth's funding arrangements.
- 8.2 In the context of ICT and the platform and software tools which PHNs deploy, it is simply incorrect for the Applicant to state that because PHNs undertake their activities within their own defined geographic regions that there is a very low risk they could infringe the cartel conduct provisions. Put simply the entire underlying purpose for the Authorisation granted by the ACCC in 2019 and now sought by this Application is to permit those geographic boundaries to be wiped away, or made irrelevant.

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- 8.3 There were good reasons to support the PHNs purchasing at a discount centralised data storage space (noting our above submissions that the Applicant has decided not to report outcomes to the ACCC from that endeavour to demonstrate those benefits), however it is quite a different matter altogether concerning the proposed monopolisation of an existing and thriving competitive market for 3rd party data extraction, de-identification and analysis and reporting software systems.
- 8.4 Contrary to the Applicant's statement at [2.2.2] that the proposed conduct has a "low prospect" of substantially lessening competition, the purpose of the proposed conduct is to wipe out the competition and to create a monopoly provider. The statement at 2.1.14 makes clear that all PHNs will be prohibited from deploying Primary Sense 2 in competition with the unincorporated joint venture PHI. Furthermore, at [2.4.2] the Applicant makes clear that the intention during the authorisation period is to negotiate contracts with all PHNs so as to effectively establish, maintain and progress the proposed conduct. That conduct is unquestionably exclusionary.
- 8.5 The identity and bona fides of the proposed manager of Primary Sense 2 within the PHI remains a mystery.

Poor Outcomes

- 9.1 At item 2.1.4 PHNs were established to commission health services in need. Is the development of software applications appropriate under this legislation? 80 GP clinics are using the Primary Sense platform in 1 PHN. Yet 30 PHNs across 6,000 GP clinics have opted to use alternate software applications when given market choice.
- 9.2 At item [2.1.5] there is no evaluation to demonstrate that this capability is any different from the current market offerings.
- 9.3 The Primary Sense platform is not subject to market forces and not required to be a viable product in market if only used for the purpose of the PHNs. It is not subject to typical market competition.
- 9.4 Authorisation from the ACCC for the proposed conduct for a period of 10 years will permit anti-competitive behaviour that will stifle the private sector. The healthcare sector is already significantly behind other industries, by as much as 10 years compared to the technology evolution in Australia's finance industry.
- 9.4 Any Rationale for the proposed conduct -
 - (a) Existing platforms are purpose built to align with PHN Objectives PHNs will dilute their ability to focus on improved healthcare outcomes if they choose to become software developers as well. Software application, a specific core competency, should be managed by technologists who are experienced in this area. PHNs should be focused on understanding new models of clinical care and how to support healthcare providers to improve patient outcomes. These are disparate skills sets and misaligned core competencies.

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- (b) Cost Savings are Unlikely 28 PHNs are already receiving the benefit of economies of scale by utilising a common data collection platform and patient to population health informatics platform. PHNs currently pay 16.3c per patient record for a whole population health management platform including data collection, data standardisation, data analytics, risk stratification, clinical decision support and planned and opportunistic care management. This includes quality improvement software applications for 6,000 General Practices and Aboriginal Medical Services.
- (c) Project & Infrastructure Synergies Pen CS software applications and GP data is already in situ on PHI at scale for 14 PHNs, which demonstrates synergies with Pen CS ecosystem. Primary Sense 2 is yet to prove itself in this arena and is by no means unique.
- (d) Clinical Improvement is not unique to Primary Sense. The capabilities that Primary Sense espouse are not unique. Pen CS serves privacy-preserving real-time data visualisation, privacy-preserving on-demand data linkage for whole patient journey modelling, patient-specific clinical alerts, delta data collection, ongoing clinically-informed data quality assurance, data sharing for the advancement of medical science and integration with innovative care plan tools, integrated team care tools and other applications via the Topbar market place.
- (e) Greater PHN responsiveness is Unlikely on the contrary, private companies like Pen CS are highly responsive, agile and cost effective in meeting changing environments fast and effectively. This has been proven over the years with PIP QI, Bushfires, COVID-19 and the Vaccine rollout. The challenges have always been the data governance arrangements that have hindered innovation or PHN due diligence re: process. It has never been technology that has stalled progress.
- (f) Improved Health Outcomes are not proven by Primary Sense real-time delta data is only the first step in better population health management. The true benefits come from creating one integrated health system. There is no evaluation of Primary Sense against other innovative PHN projects to demonstrate it is fit for purpose above its competition. In fact, an investigation would reveal that other projects currently underway are utilising more sophisticated machine learning and innovative technology solutions to deliver improved patient outcomes.
- 9.5 No evidence is provided by the Applicant to demonstrate a public benefit that it intends (and can be relied upon) to deliver regarding the following items:
 - Data collection, standardisation and delivery of de-identified patient data from General Practices to Primary Health Networks (PHNs) to inform commissioning of services in need and risk stratification of patients to deliver value-based healthcare.
 - Excellence in understanding capability and infrastructure constraints across 6,000 General Practices and Aboriginal Medical Services, to enable successful data collection and submission to PHNs despite the variance in digital maturity.
 - Population Health informatics platform that delivers Data Dashboards, Clinical Decision Support and Risk Stratification for informing population health management for PHNs and advice and guidance to inform healthcare providers, at point of care.
 - Privacy-preserving data linkage services that may inform health policy and commissioning
 of services in need for each PHN, amongst other government organisations, with the
 intention of reducing potentially preventable hospitalisation.

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- General Practice Clinical decision support applications that support healthcare providers to

 better manage patients with chronic disease and 2) focus on 'prevention' to reduce the
 onset of serious illness, where possible.
- 9.6 In addition to the technology platform used by PHNs, 3rd party providers deliver:
 - National reports for the Department of Health Practice Incentive Program Quality Improvement Initiative (PIP QI)
 - Australia-wide Training for PHN, General Practice and Aboriginal Medical Service teams both in-person and via webinars online.
 - Customer Service Delivery and Support accessible 9am to 5pm Monday to Friday.
 - Account Management Service Delivery for all PHN customers.
 - PHN resources including User Guides, Training Videos, Documentation and Brochures as required.

Yours faithfully,

Edweana Wenkart CEO

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