Australian Government
Department of Health

Deputy Secretary

Will Doolan
Coroner's Registrar
Coroners Court of Victoria
65 Kavanagh Street
SOUTHBANK VIC 3006

Investigation into the death of Ian Fraser – Court ref: COR 2019 006921

Dear Mr Doolan

I am writing to you regarding the findings of Coroner Caitlin English (letter dated 2 March 2021) and amended findings (letter dated 6 May 2021), requesting the Therapeutic Goods Administration (TGA) response to recommendations made by the Coroner in relation to the investigation of Mr Ian Fraser's death.

Since receiving the request from the Coroner, we sought further information and clarification from the Court on several occasions regarding the specific medical device referred to in the Coroner's findings to prepare this response, and have liaised with Cerner (the manufacturer), the Victorian Department of Health, SaferCare Victoria and the Australian Commission for Quality and Safety in Health Care (the Commission) on the matter.

The TGA takes the Coroner's recommendations very seriously and has carefully considered them. It was found that not all of the Coroner's recommendations fall within the remit of the TGA. This is because Electronic Medical Records (EMRs), the main contributing factor attributed to Mr Fraser's death are generally not considered to be therapeutic goods or medical devices under the *Therapeutic Goods Act 1989* (the Act), sec 41 BD.

Our investigations identified that the EMR referenced in the report is the PowerOrders software manufactured by Cerner. The software does not directly diagnose, treat or make a recommendation or decision about the treatment of a disease, condition, ailment or defect, and as such does not meet the definition of a medical device under the Act. Consequently, it is not subject to regulation by the TGA.

The Australian Register of Therapeutic Goods (ARTG) entry number 221842 referenced in the Coroner's report covers other Cerner products such as the VantageRx Database and the addVantageRx software development kit (SDK), which are clinical drug databases intended to assist clinicians recommend medications with accurate dosage and provide information on drug interaction concerns. These products meet the definition of a medical device under the Act and are regulated by the TGA. As part of its regulatory oversight the TGA will conduct a surveillance post market investigation into these products to ascertain any concerns or trends that may require regulatory action.

The TGA will continue to work closely with the Commission and other government agencies to support, promote the development and adoption of international industry recognised standards for the use of these software products in healthcare settings.

The Coroner is seeking response to four recommendations to which I set out comments below.

1. **Reassign the risk level of electronic medical records (EMR) to a risk level that requires assessment of and compliance with a usability standard. Develop standards in conjunction with key stakeholders (for example, the Commission), State Government departments and digital health officers and relevant overseas agencies)**

There are two parts to this recommendation. In relation to risk classification, in 2020, the TGA publicly consulted on the scope of regulated software products (and their risk classification) to clarify what is, what is not and what should be, regulated by the TGA. We also undertook a rapid literature review and interrogated data in our post market reporting and surveillance systems to inform our considerations. Information about our process, including submissions received from the consultation are available on our website.

The consultation identified software products not considered to be medical devices. This included software to assist in the management of prescription information, including real time prescription monitoring, or software that provides support to healthcare professionals to enable ordering, checking and recording of medicine administration. The TGA specifically sought views on whether such products should be regulated by the TGA, which was not supported.

Therefore in January 2021 based on the feedback, the Australian Government endorsed amendments to the regulation of software based medical devices (Therapeutic Goods (Excluded Goods) Determination 2018). The amendments clarified the boundary of regulation for software and confirmed the exclusion of a range of software products including EMRs. These changes took effect in February 2021 and mean that software products excluded from regulation include those intended to:

i. enable communications, including the transmission of patient information, for the purposes of supporting the delivery of health services
ii. be used for clinical workflow management
iii. be used for the administration or management of health processes or facilities (including financial records, claims, billing, appointments, operating theatre management, hospital bed management, schedules, business analytics, admissions, inventory and workflow)
iv. be used for the sole purpose of providing alerts to health professionals in relation to patient care
v. be an electronic health record (however named or described) for use in clinical practice by healthcare providers to collect, use, disclose and otherwise manage patient clinical data within or between healthcare facilities.

It is important to note that at the time of Mr Fraser's death, the EMR was not considered to be a medical device and recent amendments enacted make this clearer. Whilst the TGA has no immediate plans for reassigning the risk level of EMRs at this stage, we will continue to monitor reports and feedback in relation to EMRs, and if we receive reports of issues and patient safety events about the current excluded products (such as EMRs), the TGA may consult further if refinements or changes are needed to the current regulatory requirements. It is important to note, that whilst we do not regulate EMRs, over time if the EMR becomes more sophisticated and includes more features, so that it then meets the definition of a medical device, it would become subject to TGA regulatory oversight. Our oversight would require demonstrated evidence that the manufacturer has applied appropriate usability requirements, for example, standards.

In relation to the second part of the recommendation, the TGA is not a standard setting body, however we actively contribute to standards development for products that are defined as medical devices, and also collaborate with other stakeholders where devices could through technology

evolutions, become a medical device. The TGA also will continue to work closely with software vendors, relevant state and territory departments, their digital health officers and the Commission to educate the health software industry as to the expected standards and safety requirements for medical devices. The TGA participates in international and Australian standards development and will continue to advocate for patient safety in the design and development of software for use in healthcare.

The Commission has developed documents and other resources to provide guidance to hospitals implementing electronic medication charts, and software vendors on the information requirements and workflows to ensure safety and quality. For example, the Electronic Medication Management Systems: A guide to safe implementation and https://www.safetyandquality.gov.au/publications-and-resources/resource-library/electronic-medication-management-systems-business-requirements-addendum-electronic-medication-management-guide-safe-implementation-3rd-edition (2019).

The Commission has also developed Guidelines for the on screen display of medicines, to assist software vendors to ensure their products meet quality and safety standards https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-guidelines-screen-display-medicines-information (2017). These documents are all relevant to this Cerner product and other products for use in similar healthcare settings.

We are already in discussion with the Commission about a number of software related products including digital health apps, clinical decision support systems and a process to review the above mentioned guidelines, along with the relevant state and territory government departments. Digital healthcare is a complex and emerging area and as such, the TGA has also raised the matter of EMRs and clinical decision software support with the Australian Digital Health Agency.

2. Develop pathways for users to report adverse events involving software as a medical device (SaMD), similar to the pathways existing for other medical devices.

The Coroner's recommendation has been implemented prior to the receipt of the Coroner's findings.

Software as a medical device is subject to the same adverse event reporting requirements as other types of medical devices. These requirements include the mandatory reporting of serious adverse events and near adverse events to the TGA through the Incident Reporting and Investigation Scheme (IRIS) by medical devices sponsors and manufacturers.

Hospitals, healthcare professionals and the public can also submit reports to the TGA through IRIS on a voluntary basis. In addition to the recent consultation on proposed enhancements to adverse event reporting for medical devices, the TGA is exploring the potential for the introduction of mandatory reporting of adverse events by healthcare facilities as outlined in *An Action Plan for Medical Devices*. Preliminary discussions with all state and territory governments and the Commission on this proposal has occurred in recent months.

I do acknowledge however, that there is varied and in some cases, limited awareness of the reporting pathways by software vendors – particularly for vendors that are new to regulation. We are implementing a range of initiatives to increase awareness about reporting, including being clear about what constitutes an adverse event, specifically as it relates to software (as the impact may not be as readily identified compared to, for example, when a patient experiences side-effects from a medicine or from an implanted medical device). We have been working closely with the Medical Software Industry Association over the past 12 months regarding regulatory obligations of vendors and this will continue, including for mandatory reporting of adverse events. We will continue to promote reporting pathways to state and territory health departments, healthcare facilities and the Commission when issues are identified with software-based medical devices.

3. Assessment of EMR vendor improvements made in response to incidents for usability

The TGA does not regulate the EMR implicated in the death of Mr Fraser and is not able to assess software improvements made in response to adverse events or incidents for these products.

However, I understand that Victorian Department of Health's Clinical Informatics Council is working with its relevant health services and the EMR vendor to assess the changes made in response to this issue.

With regard to TGA's role, we undertake investigations of adverse events associated with the use of medical device software and apps which is supported through IRIS and the TGA's Uniform Recall Procedure for Therapeutic Goods (URPTG). Under the TGA's post-market framework, the corrective and preventative actions implemented by a manufacturer are assessed to ensure appropriate mitigation of any issues with the safety, quality or performance of the software. When assessing a software-based medical device (for medium and high risk devices), usability is a key element that is evaluated by our experts prior to the TGA approving a product for inclusion on the ARTG. For those devices that are Class I (low risk devices) where the vendor self-certifies they have evidence to demonstrate that their device meets the necessary safety and performance regulatory requirements – the vendor is required to specifically declare they have addressed the relevant usability standards.

4. Development of promotional material for the SaMD reporting pathway

The Coroner's recommendation will be implemented.

The TGA recognises that software vendors are relatively new to regulation and is developing a range of resources for this stakeholder group, including through co-design. Our guidance providing information on the regulations that apply to medical device software and apps (https://www.tga.gov.au/regulation-software-based-medical-devices) was published in May 2021. To support software developers and health services understand the importance of adverse event reporting and their obligations under the therapeutic goods regulations, we have commenced drafting of specific guidance to promote reporting through IRIS. The TGA is also working with relevant industry leaders including the Medical Software Industry Association and organisations such as the Australia's National Digital Health (ANDHealth) initiative and the Australian Digital Health Agency to increase awareness. Ongoing promotion of reporting pathways to a wide range of stakeholders will occur in the coming months to encourage the identification and reporting of issues associated with, software-based medical devices.

I trust that the above is of assistance to the Coroner.

Yours sincerely

Adj Prof John Skerritt

Deputy Secretary

Health Products Regulation Group

19 July 2021