Submission to the Senate Inquiry into the supply of chemotherapy drugs such as Docetaxel

Contact:
Janet Moore
General Manager
The HOCA Research Centre
11 Camford St
Milton QLD 4064

The purpose of this submission to the Senate Inquiry is to briefly articulate the critical role that the private sector plays in delivering clinical research trials in Australia and how this key contribution will be jeopardised if pharmacy providers to the private cancer care sector continue to operate at a loss.

Overview
The HOCA Research Centre was established as a not-for-profit organisation in 1990, and is a "value add "service to the Integrated Clinical Oncology Network (ICON). It is dedicated to providing patients with an opportunity to participate in new clinical trials that have the potential to prolong or improve quality of life. These studies may include the latest in cancer drugs, stem cells research or supportive care.

The HOCA Research Centre participates in primarily Phase 2 and 3 trials, where patients are afforded the opportunity to be prescribed new drug treatments, usually prior to TGA approval and PBS listing in Australia. We provide one of the most comprehensive clinical trial portfolios in Australia dedicated specifically to the oncology and haematology fields. Our current portfolio spans 17 different cancer types, with a total of 116 trials across stages 1 – 4 of establishment:

- Stage 1 – feasibility (16)
- Stage 2 – ethics (18)
- Stage 3 – open to recruit (33)
- Stage 4 – open but closed to recruitment (49)

For a number of years Australia, and in particular Queensland, has become a destination of choice for international companies looking to conduct clinical trials in the Asia-Pacific Region. With our close proximity to Asia and our long-standing reputation in producing quality and timely data as part of clinical trials, Australia is an attractive destination for clinical trials. In addition to Australia's appeal, the HOCA Research Centre has access to a network of centres with annual patient visits in excess of 75,000 per year. This large volume of patient visits has the potential to increase the number of potential patients eligible for clinical trial entry. With a dedicated team providing personalised, exceptional care to patients and families, this is a winning combination for securing a wide variety of clinical trials.

The purpose of this submission to the Senate Inquiry is to briefly articulate the critical role that the private sector plays in delivering clinical research trials in Australia and how this key contribution will be jeopardised if pharmacy providers to the private cancer care sector continue to operate at a loss, as many, if not all, have been since the price reduction on Docetaxel on December 1 last year.

This submission focuses purely on the ramifications of an unsustainable private cancer care sector on clinical research trials in Australia, and does not delve into the economies of pharmacy nor private cancer care.

Clinical research trials in Australia in the private setting
A search on the Australian Cancer Trial website, which registers all clinical trials currently in operation (and includes the Australian & New Zealand Clinical Trial Registry and Clinical Trials.gov from the US), shows a total of 1165 phase 2 and phase 3 trials in the cancer setting in Australia. According to Medicines Australia, approximately 25% of industry sponsored clinical trials are conducted in private institutions.

Based on this assumption, around 292 clinical trials (25% of the 1165) are being conducted at private institutions, with the HOCA Research Centre involved in around 40% of these.

It is difficult to determine how many oncology trials are being undertaken in QLD alone, however since the HOCA Research Centre runs four out of 10 of the private

clinical trials in oncology and haematology in Australia, it can be safely assumed that the HOCARC conducts the majority of clinical trials in this setting in Queensland.

To further enhance this assumption, although not extensively searched, there are few institutions in the private setting that conduct clinical trials in QLD, with the exception of the Wesley Research Institute and the Gallipoli Foundation at Greenslopes. It is worth noting that both of these institutes conduct research in other disciplines and are not dedicated specifically to oncology and haematology clinical trials.

The HOCA Research Centre team also aims to remain competitive on a global stage, setting key performance indicators around study start up times and patient recruitment targets. Both of these measures are of particular importance in commercially sponsored trials and enable us to attract the most sought after trials on an international and national basis.

Potential impacts on clinical trials if private cancer care services are reduced

Although the above figures offer some comfort to the Research Centre in relation to a solid pipeline of trials, it is important to continue to pursue the best possible, cutting edge treatments for the patients in our care. This endeavour is supported by a team of dedicated multidisciplinary professionals incorporating trial co-ordinators, nurses, pharmacists, data mangers and a strong team of leaders.

This integrated structure enables staff to be appropriately aligned to conduct the clinical trials with patient safety as a key focus.

The HOCARC is extremely concerned by the current chemotherapy funding crisis, not because the funding arrangements impact directly on the operations of our clinical trials, but because of the symbiotic relationship between the commercial viability of ICON's cancer care services and the Research Centre.

Our clinical trial co-ordinators work primarily in the HOCA day hospitals, which operate under the ICON banner, where they can be close to patients, pharmacists, nurses and physicians. Although the HOCARC is governed separately to ICON and operates as a not-for-profit, it is dependent on the clinical environment and expertise provided by ICON to participate in clinical trials.

If ICON is unable to operate profitably as a result of insufficient re-imbursement under the PBS for the delivery of chemotherapy, it could jeopardise the sustainability of the HOCARC.

Not only would we have limited or no access to the large number of patients needed to participate in clinical research trials, but we would no longer have access to the physical settings (HOCA day hospitals) where we currently run the trials.

While many sponsored clinical trials are conducted in the public sector, the infrastructure within the system would not be sufficient to provide the number of cancer-related trials currently supported by the HOCARC, thereby limiting the number of cancer trials offered to patients, particularly in Queensland. This would be an unfortunate and devastating flow-on effect for cancer patients and their families.

Furthermore, HOCARC's inability to participate in clinical trials would have serious repercussions for the broader cancer clinical trials market in Australia, given the

volume and variety of clinical trials conducted by the HOCARC. We are seriously concerned that pharmaceutical sponsors would look to other markets if there were any disruption to the Australian private cancer care setting, a shift that may result in long-term disenfranchisement for cancer research centres in Australia participating in phase 2 and 3 trials.

Potential impacts on patients if clinical trials are stopped or reduced
The treatments that Australian cancer patients are fortunate enough to have ready access to today under the PBS all emerged through clinical research trials.

The need for clinical trials continues to grow with the rapid emergence of new treatments, such as targeted therapies, which provide better outcomes for patients with fewer side effects.

Researchers and treating physicians hope that in the foreseeable future many cancer types will be either curable or become manageable chronic diseases. Australian patients are well positioned to be among the first in the world to experience longevity post cancer or with cancer.

Most of the patients who participate in Phase 2 and 3 clinical trials through HOCARC and other research centres in Australia are not necessarily expecting a cure, but rather they hope for prolonged quality of life – more time to enjoy with family and friends. Many patients are afforded additional months, or even years, as a result of clinical trials. These treatments then provide the building blocks for further research and even more successful results for future patients, with the hope of eventual remission.

If the cancer care centres through which patients access clinical trials are not able to provide chemotherapy affordably, they will cease or reduce services, which will have an immediate and devastating flow-on effect for Australian patients currently participating in clinical trials, and those well into the future.

We would urge the Senate Committee to adopt a global view of the issue and consider the far-reaching and serious ramifications for Australia's cancer patients, cancer care providers and cancer researchers if there is prolonged, inadequate funding for the provision of chemotherapy in Australia.

Ends