health technology assessment. Thirdly, the government could commission research to where its agencies have identified there is truly a gap in the evidence needed for their decisions.

Barriers that cause delays in getting new medicines to market relate to the process of registration and to reimbursement. Situations exist where off-patent drugs could be repurposed and used to treat new conditions. There are also situations when an active drug is not being pursued by a sponsor, to have it registered for an active indication. Actions could be directed to commission and fund clinical trials in rare diseases involving the repurposing of those old drugs. For therapies and technologies that have insufficient evidence to support reimbursement in the Australian market, enable a pathway whereby the PBAC or MSAC could commission the research on that new agent only, in order to collect and support the reimbursement data. It concerns us that delays between the TGA and PBAC funding is often greater than 12 months, particularly in the case of life-prolonging and life-sustaining drug reviews.

For Australia to be dynamic and responsive, but retain the necessary diligence in fiscal management, the government could, firstly, provide a simplified pathway to TGA registration for novel therapeutics or technologies. If it's approved in a similar jurisdiction, have a process whereby we can readily accept and move forward with a review for our reimbursement. Secondly, implement a pathway to expand the TGA labels for TGA registered drugs. For example, a drug that's indicated in Australia for a disease indication, and subsequently it's discovered that a reputable agency overseas accepts it in another indication, we could have a pathway where our TGA accepts that indication and that label for use in Australia. Thirdly, we could establish a pathway of conditional drug reimbursement whereby ongoing reimbursement after a period was dependent on the generation of the supportive data from internationally or domestically collected data. This could be best achieved by drug access linked to data acquisition by clinical trials on national registries. I refer you to our detailed discussion in our submission, 112, and hand over to you, Chair, for questions.

CHAIR: Thank you. Mr Murphy.

Mr Murphy: Thank you. The Leukaemia Foundation is a patient organisation representing 110,000 Australians living with a blood cancer or a blood disorder: leukaemia, myeloma, lymphoma or the related disorders. We are also the secretariat for the Blood Cancer Taskforce, which Professor Seymour co-chairs and Delaine is a member of the task force as well. We have brought together the community of interest to solve for the challenges of access to care and support for people living with blood cancer around the country. Professor Seymour has already talked about the relevant challenges around access to novel and specialised therapies, but I want to reiterate the need for patients to solve for these problems with the whole community.

There are barriers to access clinical trials. There are additional barriers for regional patients and those in remote areas. We've talked about the disparity of survival outcomes. There are barriers to access accurate and timely diagnosis and access to genomic and genetic testing, as well as barriers to evidence development to support both the PBS and the MBS listings. Throughout all of these systems the voice of the patient and the access of the consumer to being involved in decision-making is subpar. We would like to see some changes in the way the consumer voice is seen.

We know that the situation in Australia is very complicated and complex, but that doesn't mean we can't find solutions to solve for it. There are examples of tests in other jurisdictions and diagnostics that should be readily available in Australia, which Delaine has previously mentioned. But we know that in Australia if a therapy is not MBS or PBS listed it's highly unlikely that a patient would get access to it. Our system is geared to PBS listing, or MBS listing through the public systems, as the vehicle for access. So if they can't access through those systems individuals must access privately or through compassionate use programs from pharmaceutical companies or other sponsor companies or they forego treatment. We find that to be a very difficult position for a lot of patients to find themselves in, in the gap between a TGA registration to a PBS listing. So we're looking to find ways to speed up the process for people to gain access for critically important diseases.

The Leukaemia Foundation's State of the Nation report, which we produced in 2013, was the precursor for the federal government supporting us to create the Blood Cancer Taskforce and the creation of the National Action Plan for Blood Cancer last year. We see the 21 recommendations are really critically important as the consensus of the whole community to drive reform and ultimately to save not only the 13 per cent of lives, the 22,000 lives Professor Seymour talked about, but more lives into the future if we get our system ~~in play~~ to be more effective today. Thank you very much.

CHAIR: Thank you. Professor Hansford.

Dr Hansford: Thanks for the opportunity to present on behalf of our group nationally. A thousand children per year are diagnosed with cancer in this country. Thankfully, with our modern techniques and treatments, we

Prof. Seymour: On the first-round diagnostics, blood cancers, although cumulatively common—there are about 17,000 to 18,000 cases a year—individually are rare. That's made up of more than 80 different entities. It's a bit like going to Grand Central Station; there are plenty of trains there, but which one do you want to get on? So making sure that you are on exactly the right train is critical. And having experienced histopathologists—so people who see large volumes of these, and that means centres of excellence, centres of reference, and access to molecular diagnoses. So no longer is it looking down the microscope and saying, 'This looks like a breast cancer.' The issue is: which aberrations in the genetic make-up of this cancer are driving the process? And that comes down to personalised diagnostics, which are not funded and rely on research—

Mr ZAPPIA: So it comes down to funding?

Prof. Seymour: Yes. So centres of excellence to ensure volume, and then funding of the molecular diagnostics.

Mr ZAPPIA: Thank you. Mr Murphy, how do we get some consistency across what the states and the federal government are doing?

Mr Murphy: The jurisdictional issues are complicated. The federal government has responsibility for access and decision-making around the purchase of drugs, therapies and diagnostics, and the states have responsibility to utilise them in public settings. We know that there are disparities in the way the states budget through the hospital systems, which creates challenges for access to already approved therapies. That's one of the things we would like to solve in our enabling access working group—to identify which therapies and diagnostics have federal support but are limited in their use because of state budgetary issues.

There are a whole raft of other challenges around clinical trial jurisdictional responsibilities, which we've touched on already, about workforce development, ongoing funding of workforce. We fund, as the Leukaemia Foundation, clinical trials, support to ALLG, and we use the ~~good~~ donations of the Australian community to fund that. And that is absolutely at-risk money. So there are real challenges for continuity of clinical trial activity as well.

CHAIR: Dr Allen?

Dr ALLEN: Thank you very much your excellent work across a very important area. My question goes to the issue we've heard about from other people as well relating to how we attract more clinical trials to our shores. We've heard a lot about how much we can make things more efficient and, from a regulation point of view, the cost of activity, how we run trials, is also important. We've also heard that there's a low uptake of patients. In your particular field of blood cancers are we getting patients onto these trials, would it make it a more attractive destination, and, if we're not getting to the patients, how would we do that? Is it the ivory towers or is it, potentially, through GPs?

Ms Smith: I'll take that question, to start. The regulatory framework in Australia for the conduct of clinical trials, definitely speaking from the academic cooperative group sector, is very good. We have good ethics review and regulatory systems in Australia. We're a middle-tier country, according to the data in ANZCTR. It says that we have quality; our data is reliable and reproducible and very meaningful. So we've got a lot of positives in Australia for the conduct of clinical trials. We don't have a sufficient enough workforce. We don't have a career structure for those who want to work in clinical trials, and the hospitals lack the embedding of clinical trial activity in their actual units.

It always strikes me, when I speak to hospital executives, that they somehow think that if you're running a clinical trial you're creating new patients that didn't exist before. But these patients already have cancer. From our area, they already have blood cancer. They've already got a diagnosis. They've already got the disease. We're not pulling them in from somewhere that didn't exist before and bringing new activity to the hospital and overburdening the hospital. We're offering an opportunity to a treatment, a new novel therapy, a new technology, to be trialled to then move to, hopefully, gather the data to then implement that in Australia. So a lot of it comes down to the embedding, trying to come up with solutions.

I think they do need to come from the federal government. The hospitals are state based. A big push from the federal government could make a big difference here at the state level, with the hospitals, with the embedding of clinical trial activity and the funding to groups that do perform quality cooperative national clinical trial work, such as ANZCHOG, where Professor Hansford's from, and our group at the ALLG.

Dr ALLEN: It's a bit along the lines of St Jude in Memphis, Tennessee. Every person who comes to that hospital gets a patient compact that they will be offered a clinical trial.

Dr Hansford: For paediatrics, we embedded in our practice; it is absolutely what is required. Our problem is volume. We have large patient volumes. We have a small clinical trial staff. When we have a trial open, we enrol