

Media Coverage

Company: AusBiotech
Date: 7 February 2011
Publication: Australian Financial Review
Page: 53

Buchan

Business Strategy | Communication | Public Policy

Losing our grip on R&D

Drug research has been a major success story in Australia, but now developing countries are starting to become serious competitors, writes **Peter Roberts**.

Mitch Kirkman employs a sporting analogy to explain his fears for one of Australia's biggest research-based export industries. As manager of international clinical research for Novartis Pharmaceuticals he has ridden a boom in research and development spending on the clinical trials that test the safety and effectiveness of new drugs.

"I don't export vials [of drugs], I export data points from clinical trials," says Kirkman. "Clinical trials in Australia are a great success story."

The trialling of potential new drugs has grown tenfold in Australia since the 1990s and is now an industry worth \$700 million a year encompassing 700 trials and more than 19,000 patients.

But it faces increasing competition from developing countries with rapidly improving healthcare systems and lower costs.

"It you think of our early success at the Olympic Games, that was due to natural ability," says Kirkman. "It is the same for clinical trials — we have been successful but it has been natural ability. But it is no longer enough to keep us at the cutting edge."

Australia responded to an early Olympic malaise with a focused Institute of Sport, but is slow to react to the mounting effects of globalisation on manufacturing and clinical trialling, the two pillars of our \$15 billion pharmaceutical sector.

Australia's multi-cultural population was an early strength in recruiting diverse groups of patients for clinical trials, but this advantage is being eroded as developing countries lift their game. Australia remains competitive for early-stage clinical trials, which involve relatively small numbers of patients and relatively sophisticated medical supervision. But it is losing out on the very large-scale phase 3 trials to the likes of China and Brazil.

"Phase 3 costs [in Australia] are escalating rapidly," says Mark Tennyson, executive medical director of innovative drug developer AMGEN. "But Australia does have a reputation in this area as a clever country and we actively work to support that."

The benefits of clinical trials to Australia are more than economic. Trialling new drugs, treatment regimes and medical devices keeps clinicians up to speed with the latest technologies. Patients suffering diseases that cannot be treated with existing medicines also have the potential to access possibly life-saving medications that are still under development.

"Two-thirds of clinical trials are funded by the private sector and 55 per cent are carried out in public hospitals," says Brendan Shaw, chief executive of industry group Medicines Australia. "It is a great example of the private sector working with health and with the research base to develop new drugs... and improve health outcomes."

The biggest frustration for the sector is the slow pace of regulatory reform first recommended to the Howard government in 2005. The key problem is a lack of co-ordinated regulation governing the establishment and running of trials.

Companies find it difficult to recruit large



The pharmaceutical industry is worth \$15 billion a year to Australia.

Photo: MICHEL O'SULLIVAN

numbers of patients through multiple hospitals and clinics as they need separate ethical approvals from the country's more than 250 Human Research Ethics Committees. Delays in meeting patient recruitment milestones are holding up the completion of trials, affecting Australia's international reputation for reliability.

"We still don't have single ethical approval in Australia [for clinical trials] and we have been working on it for years," says Novartis's Kirkman.

The federal government's Harmonisation of Multi-Centre Ethical Review (HoMER) initiative has been working to smooth the approvals process since 2006 and most recently reported to the government in October. Pilot programs are under way to "build trust" in a national approach within 40 institutions.

The National Health and Medical Research Council (NHMRC), which is managing HoMER, recently released for public comment a set of draft standard consent forms for participants in clinical trials.

"We are halfway through the accreditation of ethical committees," says Warwick Anderson, chief executive of the NHMRC. "We have certified 16 [of 40 committees], and we have told five to go and try harder."

At a recent Sydney conference there was a general despondency that reform was moving slowly while competitor countries were gaining market share. After years of growth above global averages, the number of trials in Australia has begun to fall for the first time, says Medicines Australia's Shaw.

"HoMER has been moving slowly," he says. "It has been around for a long time and should have been fixed by now."

There was more open concern at the conference at Canberra's failure to implement two key findings of its 2008 Pharmaceutical Industry Strategy Group inquiry headed by CSL CEO, Brian McNamee.

McNamee highlighted two substantive recommendations including increasing Australia's attractiveness as a location for clinical trials by reforming multi-centre trials and through e-health initiatives. According to AusBiotech CEO Anna Lavelle, national access to patient records is needed to support clinical trials.

"The lack of a consistent electronic record system that can be accessed remotely for

The biggest frustration for the sector is the slow pace of regulatory reform, first discussed with the Howard government in 2005.

clinical trial monitoring increases the costs and time," she said in a submission to the government.

Pfizer Australia managing director John Latham says everyone in the sector was in violent agreement with McNamee's recommendations on clinical trials but they were made "a long time ago".

"We need to fix a few things," says Latham. "Everyone was in agreement 18 months ago but these things have to be implemented."

Pfizer recently downsized its clinical trials staff from 65 people to 14.

"Yes, we are moving more of our clinical work to developing countries," says Latham.

Late in 2009 the government established a separate Clinical Trials Action Group to speed up the reform process. The group has taken public submissions and completed a report which has yet to be released.

"We know the group involved has done a lot of good work on this and we are keen to see the release of its report so we can get on with fixing it," says Shaw.

The industry is also positive about the government's tax credit proposed to replace the long-standing R&D tax concession. The credit would provide upfront benefits to small, start-up companies and make R&D 10 per cent cheaper in Australia.

However, the Coalition opposes the legislation. And after a number of substantial revisions to what are extremely complex definitions of the nature of R&D, the credit is still before Parliament and its future is uncertain.

The government does support R&D through direct grants schemes and supports major investment in R&D infrastructure on a case by case basis. Blood product and vaccine company CSL received \$30 million from the federal government towards a \$235 million R&D facility built recently at Broadmeadows in Melbourne.

"The money was highly conditional on delivering project milestones and on delivering jobs," says Jeff Davies, a CSL executive vice-president. "The government worked us very hard in the process."

CSL will spend \$340 million on R&D this year, according to Davies who is responsible for the Broadmeadows site.

However, the federal government does not provide similar subsidies to purely manufacturing investments in deference to World Trade Organisation rules. A strategic investment fund to support new investment in manufacturing was the second major focus of the McNamee inquiry.

Factories are closing around the world as companies respond to globalisation. Pfizer, for example, is shutting 80 global manufacturing locations, leaving only 60 by 2015. However, this will include the four existing Australian plants because of niche specialisation, cost containment and product safety and quality, says Pfizer's Latham. The company's local production and Asian exports have been on the rise over the past four years while staff has been cut by a fifth.

Says Latham: "The burning platform has been there for us."

The Australian operation competed in 1998 within Pfizer globally to be the site for a new factory to manufacture the active ingredients of drugs but missed out. While construction and running costs were cheaper in Australia, Singapore won the investment through incentives.

"Those manufacturing plants that are operating [in Australia] are operating without incentives," says Latham. "When people are closing plants worldwide you are not going to be attracting people to Australia to open plants."

Pharmaceuticals have been an economic success story since the early 1990s that culminated in 2009 with exports of \$4.12 billion, exceeding automotive exports for the first time.

However, Novartis's Kirkman points to threats from globalisation that are causing investment in manufacturing and clinical trialling to move to the developing world at the expense of the developed, making reform is urgent.

"Traditional locations [like Australia] are in for a lesser slice of the cake," he says.