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Dear Clinical Trials Action Group

Submission to the Clinical Trials Action Group (CTAG) in response to call for advice on ways to strengthen Australian's position as a destination for clinical trials.

Please find following the AusBiotech submission, which encompasses feedback from consultation with its 3,000-strong membership. AusBiotech is the national industry organisation providing representation and services to promote the growth of Australian biotechnology.

Following AusBiotech involvement in the Pharmaceuticals Industry Strategy Group (PISG), I welcome this initiative, which responds to the PISG's recommendations to investigate priority reforms to the clinical trials operating environment to make Australia a more attractive location for investment and activity.

Clinical trials are pivotal to the biotechnology sector and thought to be worth $450 million annually to Australia. Australia needs a vibrant, productive, efficient, internationally-competitive and world-class clinical trials industry to support local biotech development within Australia:

- If Australia is not internationally competitive it will be harder for local biotech to attract foreign investment into Australia;
- If Australia is not recognised globally in clinical trials, local data may be less acceptable for licensing purposes;
- If the clinical trials industry doesn't improve its productivity, local biotechs will be disadvantaged, or will be prompted to move trials off-shore, losing a greater share of potential returns to the Australian economy.

Australian biotechnology evolves from the high-quality, basic medical research, and a strong translational capability is required to support progress through the early stages of drug development. Clinical trials are a key part of this, but if the preference is to complete this off-shore, there will be a 'domino effect' on the pre-clinical service providers and development manufacturing providers.

Key concerns

The following points are key to the biotechnology industry's concerns:

In a *"Submission in response to the 'exposure draft' of the Tax Laws Amendment (Research and Development) Bill 2010, released 18 December 2009"* (05 February 2010), AusBiotech outlined a major concern about the possible exclusion of clinical trials from the R & D tax credit draft legislation. The 'exclusions list' is open to interpretation and could be understood to exclude clinical trials, which should be included as eligible R&D. The draft legislation:

- s355-35 (2)(l) may render clinical trials ineligible as they are performed for (amongst other purposes) the preparation of a regulatory requirement of the Therapeutic Goods Administration;
- may drastically reduced the eligible manufacturing processes, including clinical trials, with the expansive drafting of s355-35(2)(h);

AusBiotech shares the concerns outlined in the PISG Final Report (December 2008, point 7.2) about the features of the Australian environment that may reduce competiveness or be disincentives to conducting clinical trials in Australia. These are:

- Timeliness of trial approval - The need to obtain ethics approval for each centre of a multi-centre trial increases the costs and delays commencement, which is critical. AusBiotech applauds The National Health and Medical Research Council's (NHMRC's) Harmonisation of Multi-Centre Ethical Review (HoMER) initiative to harmonise ethics as a much-needed reform. However, the program is still in need of a mechanism to ensure compliance and cooperation across state and territory jurisdictions for the purposes of consistency and continuity;
- e-Health - The lack of a consistent electronic record system that can be accessed remotely for clinical trial monitoring, increases the costs and time;
- Patient recruitment - The limited capacity to rapidly identify suitable trial participants due to the lack of a co-ordinated network, again adds time and cost.

Recommendations

<u>R& D tax credit</u>
AusBiotceh recommends the Federal Government provide a statement clarifying the exclusions list on the R& D tax credit draft legislation, to provide certainty about the implementation of the tax credit. Specifically this should explain how clinical trials are to be supported by the program.

<u>Timeliness of trial approval</u>
AusBiotech supports the national streamlining of ethics approvals for multi-centre trials, including a uniformed national patient consent form – and suggest this is a critical issue and perhaps a role for COAG.

<u>e-Health</u>
AusBiotech advocates for the timely implementation of an e-health platform that will allow national access to patient records for the purposes of clinical trials and enable secure remote access to trial monitors.

<u>Patient recruitment</u>
AusBiotceh recommends that a formal national patient referral network be established that creates a collaborative relationship between public hospitals, universities and the biopharmaceutical industry.

Summary

AusBiotech supports the need for development and growth of the clinical trial market in Australia so that it becomes more productive and efficient and is available for both biotech development and overall health reform. In particular AusBiotech recommends the national co-ordination of policy on clinical trials across the Australian, state and territory governments to ensure cost reduction and speed to commencement, which will ultimately increase competitiveness globally and make Australia a more attractive destination for trials.

AusBiotech is available and committed to working with the Government to achieve the intended result. If you would like to discuss this submission, please feel free to contact me on alavelle@ausbiotech.org or 03 9828 1404.

Yours sincerely

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