

Funding uncertainty hinders Australian life science

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Singapore: A prominent healthcare industry leader sounded the alarm over Australia's system for approving government funding of new drugs. Dr Alan Robertson, CEO of Australian-based Pharmaxis, highlighted that delays and uncertainty around public funding for new treatments could leave patients without the medicines they need.

Australia's Therapeutic Goods Administration (TGA) is responsible for determining if products are safe and effective. Once they have been approved, another body called the Pharmaceutical Benefits Advisory Committee reviews the products for listing on the Pharmaceutical Benefits Scheme. Medicines costing more than \$10 million a year must also be approved by the cabinet.

Dr Robertson said that, "Government funding in Australia and many other countries is critical to the success of a new product, however, the approval system is in need of reform. The process is filled with uncertainties, lengthy bureaucratic delays, red tape and a lack of objective measures to determine the public benefit of a new treatment. There is no absolute truth in these funding decisions, only opinion and mathematical models that rely on inherently uncertain inputs."

Dr Robertson will speak about the problem when he delivers the "Millis Oration" at the upcoming AusBiotech conference in Melbourne, during the beginning of November. The Millis Oration is named after Emeritus Professor Nancy Millis, a pioneer of Australian biotechnology, who passed away recently. Professor Millis has been described as the First Lady of Australian biotechnology for her work in fermentation and appeared on a postage stamp as one of five Australian legends.

He also pointed out that even with the strengthening of safety regulations in recent years, regulatory approvals are relatively streamlined and clear compared to the reimbursement approval process. He said that obtaining funding, ironically, has now become the most cumbersome part of bringing a new drug to market.

Dr Robertson said that, "It took a year for our cystic fibrosis treatment, Bronchitol, to be approved as safe and effective after

the Australian regulator completed a very thorough and detailed analysis. Once it was approved for sale, however, it then took more than 18 months for a decision to be made on government funding despite a very strong patient need. There has not been a new treatment for cystic fibrosis created in over 15 years and our product was discovered and developed in Australia. Clearly, the review of cost-effectiveness should not take longer than a review of safety and effectiveness."

"I completely understand the public and government's very valid concern about the cost of new medicines. We need to keep the cost contained. Ironically, though, the delay in getting medicines to the patient means the pharmaceutical company has a shorter time in which to recoup its investment in research and development. So what happens is, the extended debate about the cost effectiveness of a product actually significantly drives up the end cost," added Dr Robertson.

Dr Robertson believes the funding system needs to be revamped to better deal with a new generation of medicines. A session on "the road ahead" will be held following Dr Robertson's oration at the AusBiotech conference on Thursday, November 01, 2012.