



The Therapeutic Goods Administration (TGA) is the regulatory agency for prescription and over-the-counter drugs in Australia. The governance structure of the TGA has changed markedly in the last 15 years. VIOLA KORCZAK argues it's time to remodel the TGA into a more transparent and impartial regulatory agency.

TGA TRANSPARENCY AND INDEPENDENCE

The TGA has been following the trend of regulatory bodies in Europe and the UK which have bowed to industry pressure to restructure their drug regulatory authorities and to accelerate drug approvals. In Australia the move towards more industry involvement was sparked by the Baume Report in 1991 which stressed the need for improved industry relations. At this time the Government also decided that industry should fund the TGA's drug approval process. A new national manager was appointed (1992) and the TGA achieved its cost recovery target of 50% by 1996/7 and full cost recovery for all activities in 1998.

The International Conference on Harmonisation (ICH) has promoted a globally standardised system of developing, marketing and regulating pharmaceuticals to meet international 'best practice' for processing applications. This underlies the move from government to industry-influenced regulation internationally.

There are obvious constraints with this regulation model. The TGA must raise its own revenue from inspection and evaluation fees, charges and annual registration fees. This has generally led the TGA to become more responsive to the industry's attitudes and practices. It is worth noting that when the UK regulator became reliant on the industry, the new director promised to reduce processing times by 24% within a year.

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Secrecy

The Medicines and Healthcare Products Regulatory Agency (the TGA equivalent in the UK) has a similar funding structure but from November 2005 has begun to disclose assessments used in its decisions, and minutes of its meetings. The Food and Drug Administration (FDA), the US equivalent, also makes results available online.

The TGA lags behind regulators in other industrialised countries in becoming more transparent. For example, provision for public access to information has not changed in ten years and no important information, such as cost-effectiveness data considered by the PBAC (Pharmaceutical Benefits Advisory Committee) for the PBS (Pharmaceutical Benefits Scheme), is available to the public. The TGA does publish the minutes from some meetings online but they are edited versions. Medicines Australia (MA), the peak body of the pharmaceutical industry, seeks to maintain the secrecy arrangement.

There are also ethical and public health concerns regarding the pharmaceutical industry's influence. New prescription drugs are tested for quality, safety and efficacy by the pharmaceutical industry — very little research is funded by government. This raises two questions. First, do shorter approval



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times reduce scrutiny of the test results? Second, are drug research priorities consistent with community need? For example, pharmaceutical companies have more incentive to develop drugs for chronic illnesses because they will be used for longer time frames.

The influence of the pharmaceutical industry, lack of transparency in processes and changes in the funding structure of the TGA over the last 15 years, have significantly reduced the effectiveness and independence of the regulator. However, UK and US reforms show that changes can be implemented.

