



Australia and its Industry Code of Conduct

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Australian BioPharma Landscape



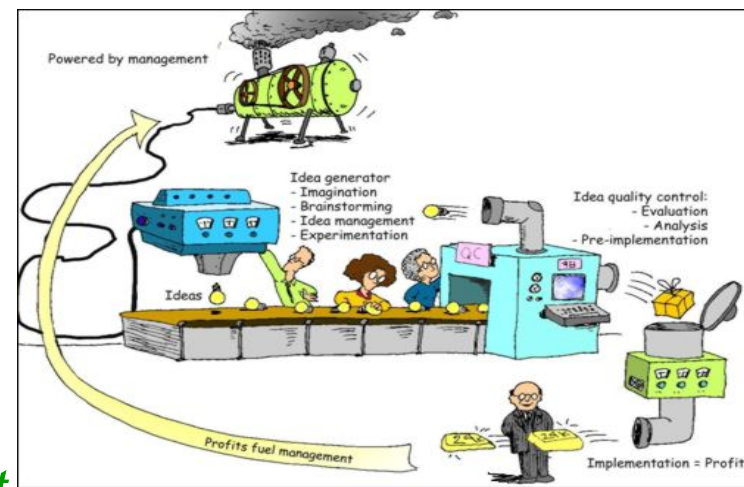
- Around 80% of Australian prescriptions are government-subsidised, with the PBS covering over 850 medicines largely comprised of branded products.
- Following Federal Parliament's approval of the **National Health Amendment (PBS) Bill of 2010**, which aims to make savings of A\$1.9 Billion over 5 years, the outlook for the local Australian Pharma industry is mixed. **It is clear that the revised government pricing proposal shows a shift towards rewarding innovation.**
- Since August 2007, the PBS has been divided into two formularies F1 and F2. F2 drugs will endure price cuts whilst F1 drugs are insulated from reference pricing, even if the mechanism of action of a F1 drug is similar to that in F2. F1 drugs which do not have bioequivalent brands can maintain higher prices according to the new formularies.
- The A\$1.9 billion planned savings will be made largely through price cuts across all products listed on **Formulary 2 (F2) of the PBS**, and the extension of price disclosure arrangements to all F2-list products (about 1,600 brands).
- Generics Coys were not included in the negotiations & firmly opposed the Bill.

What does this mean for industry?



- **Downward pricing pressure on products** will mean internal “re setting” of priorities across industry; possible withdrawal of products & decisions not to launch; all Coys will re think their future investment of resources & money.
- Nonetheless, Australia is said to be **one of the most attractive markets** for **pharmaceutical** investment in APAC primarily due to its growing and ageing population, excellent access to medicines, and fast-recovering economy. GDP is projected to be the 5th largest in APAC in 2016. In terms of GDP per capita, Australia will be ranked first in the Asia Pacific region.
- Life expectancy in Australia is 79.2 years for males; 84.1 years for female.
- **During the next 5 years**, Australia will be impacted by government action including the imposition of price cuts on drugs, the raising of standards required to achieve reimbursement of innovative therapies, and the use of economic incentives for prescribers and pharmacists to drive a shift towards generic equivalents. Evidence of the value that medicines bring to healthcare systems will be required to achieve access and funding in both developed and emerging markets.

What lies ahead.....



In today's market,

differentiation is more important than ever.

Pharma's customers increasingly are Payers (very often government departments) and patients who care about two criteria:

health outcomes and affordability.

Nonetheless, "good ethics" should always be an important pillar of a Coy's mission statement: everything else will then fall into place.

Ethical business practices are not only good for the Coy but also good for the Coy's reputation.



Medicines Australia Code of Conduct

- Is a voluntary self-regulatory code of conduct developed by Medicines Australia (MA), the peak drug industry body. The first Code was introduced in **1960** and has been developed over time to accommodate changing social, political and professional expectations.
- The **16th Edition** is now operable, effective from January 2010.
- MA states that the Code sets "the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. It complements the legislative requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act."
- It is designed to guide the promotion of prescription drugs by pharmaceutical companies in Australia. It includes standards for appropriate advertising, the behaviour of medical representatives and dealings with healthcare providers.
- Version 2 of the MA Guidelines were introduced in July 2011. Major changes provide guidance on the **use of social media, member responsibilities with regard to educational events, use of market research initiatives and interactions with student health professionals.**

Evolution of MA Code



- Marketing to HCPs was typically based on 4 main pillars: detailing to doctors, provision of drug samples, gifting and sponsoring of “continuing medical education” events. However, much has changed since the early days....as some of these strategies have been found to compromise prescribing behaviour and/or influence the independence of HCPs.

Stems from A Jaundiced View of Big Pharma:-

Celebrity doctors are paid large amounts by Big Pharma to effectively act as sales reps at “scientific” conferences.

Many doctors (KOLs) were said to be on Big Pharma’s payroll, taking what amounts to bribes, kickbacks, and other “gifts”.

Doctors are subjected to intense Big Pharma propaganda as a major part of their training in medical school.

Samples were improperly given to doctors either to be pocketed, sold, traded, misused or abused.

The Days of the Blockbuster...are gone!

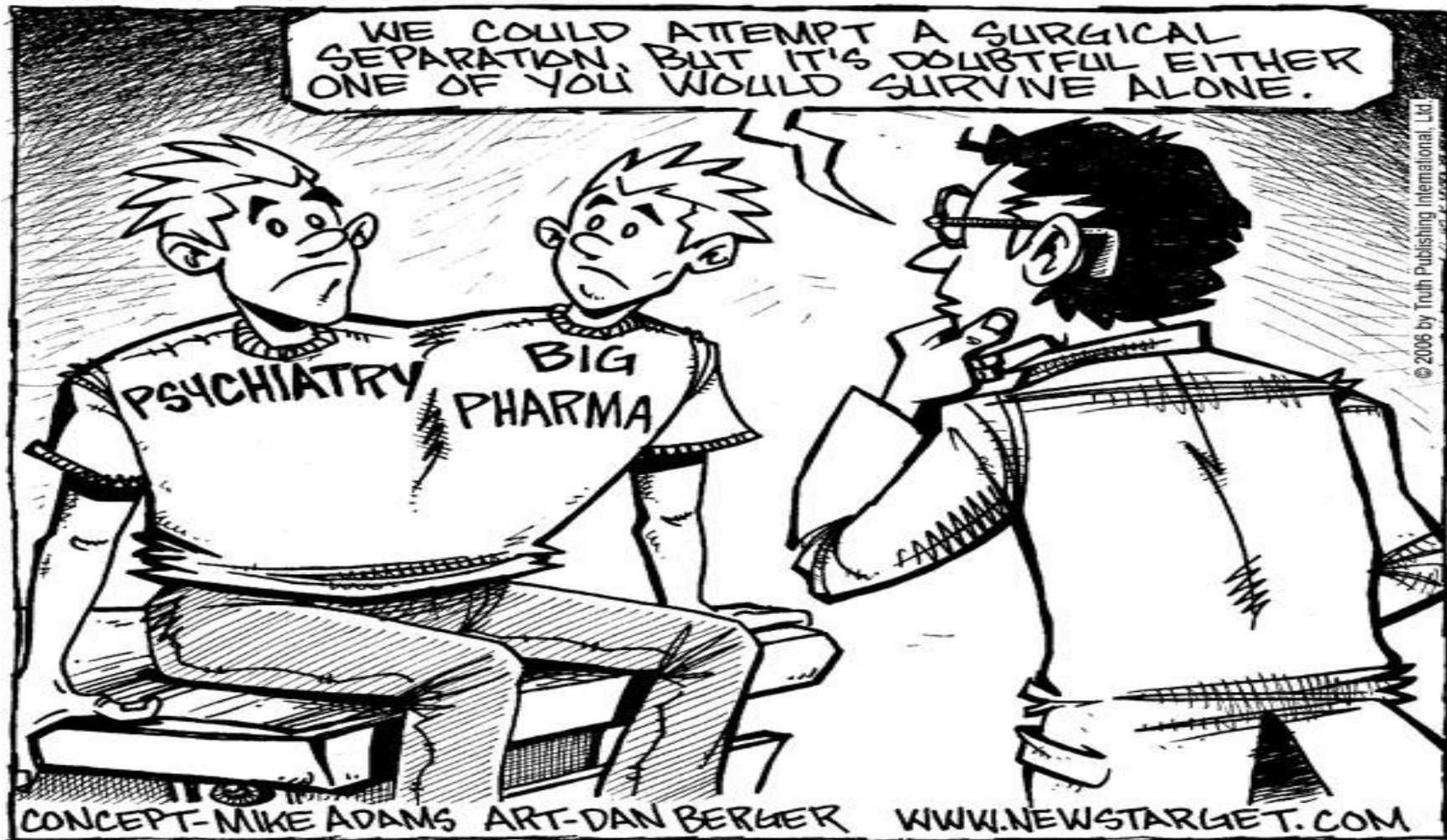
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"Here's how it works. First we discover the drug and identify the market, then we invent the disease."

As are “cosy relationships” with Doctors.

COUNTERTHINK



ACCC Review in 2006

- In July 2006 the **Australian Competition and Consumer Commission** (ACCC), approved MA's application for re-authorisation of its voluntary code of conduct. In approving the Code, the ACCC considered that there was a need for **greater disclosure of drug company funding of 'educational' events for Healthcare Providers (HCPs)**.
- The ACCC decided to authorise the Code on condition that each Member Coy complete a monthly report including **details of the venue, purpose of the event, the hospitality provided, the number of attendees and the total cost of the function**. Each Coy is required to submit the data to MA at the end of each six month period – which is then obliged to publish the data to ensure transparency.
- The ACCC also provided that a Monitoring Committee established under the Code may request further information from Coys "such as a copy of the invitation" sent to Invitees where it "suspects a potential breach of the Code. If the Monitoring Committee is not satisfied that the conduct of a Member Coy with regard to any meeting would withstand public or professional scrutiny (or would amount to a breach the Code), it may submit the matter to the Code of Conduct Committee as a “complaint” to be dealt. Sanctions follow.

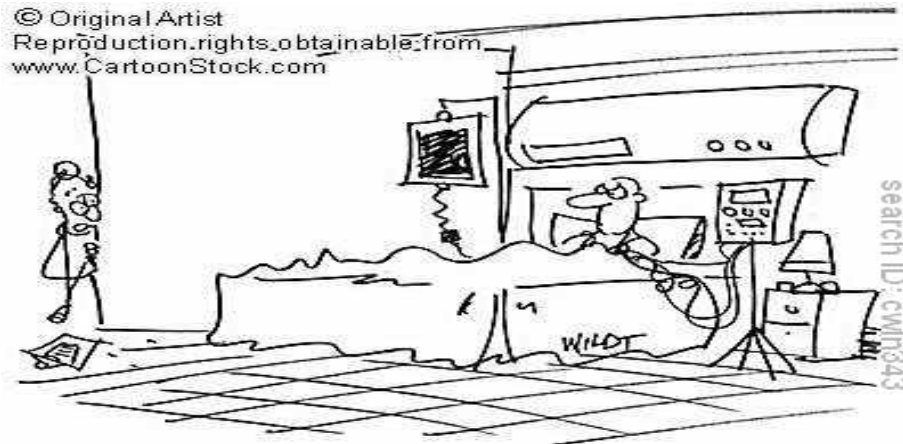
Age of Transparency

- In March 2008, MA released its first "educational events" reports. In the media release, MA revealed that the total number of events in second half of Y2007 was 14,633. The total expenditure on the events was \$A31 Million of which \$A16.4 million was spent on travel, accommodation and catering. The events were organised by 43 Coys.
- Describing the reports as setting "[a global precedent for the pharmaceutical industry](#)", MA reported that "the total number of attendances is 385,221, with an average hospitality cost of \$43 per head." MA further emphasised that "[Under the Code, the provision of personal gifts to doctors is banned. Entertainment is banned. The provision of lavish hospitality is banned.](#)"

Section 3.11 of the Code provides that "No items or services shall be offered or given to healthcare professionals unless they are sanctioned by one of" six other sections of the code. The Code does specify that in relation to educational meetings that "No entertainment* should be provided" and that "Interactions between companies and healthcare professional must not include entertainment." Moreover, the provision of meals "should not be extravagant or exceed standards which would meet professional and community scrutiny.

Focus should always be on the Patient / Medicine

- Today, greater attention is drawn between “promotional events” and “non-promotional events”, and how a Coy’s products can “add value” to patients. There is a shift away from lavishing benefits and attention on individual HCPs towards **rightfully addressing** “unmet medical needs”, enhancing “patient care”, fostering “scientific debate” and / or “sponsoring genuine healthcare initiatives”.
- Stakeholders and Shareholders today demand that Pharma Coys be guided by firm values and clear mission statements – whereby they focus their energies on **meaningful contributions to science, medicine and true patient care.**



"You'll find my bedside manner improves greatly when you're no longer contagious."

The Relationship between Industry & Doctors

- Industry possesses resources to finance R&D programs, for which the knowledge and experience of doctors is essential. Support from industry enables furtherance of medical research, scientific congresses and continuing medical education – **all of which can be of great benefit to patients** who engage in such initiatives as well as to the entire health system.
- The combined resources and knowledge of industry and the medical profession enables the development of new diagnostics tools, drugs, vaccines and therapies that **lead to advances in medicine**. Without this union, few significant advances in healthcare would be made.
- What is to be avoided are “conflicts of interest” (or **hidden dangers of influence**) which can affect the care of patients, the objectivity of doctors, and greatly tarnish the reputation of doctors and industry alike.
- Any relationship should be “arms length”, based upon professional merits, and transparent in the objectives that are to be gained by either party. **The furtherance of better quality patient care should shine above all.**

Questions?

