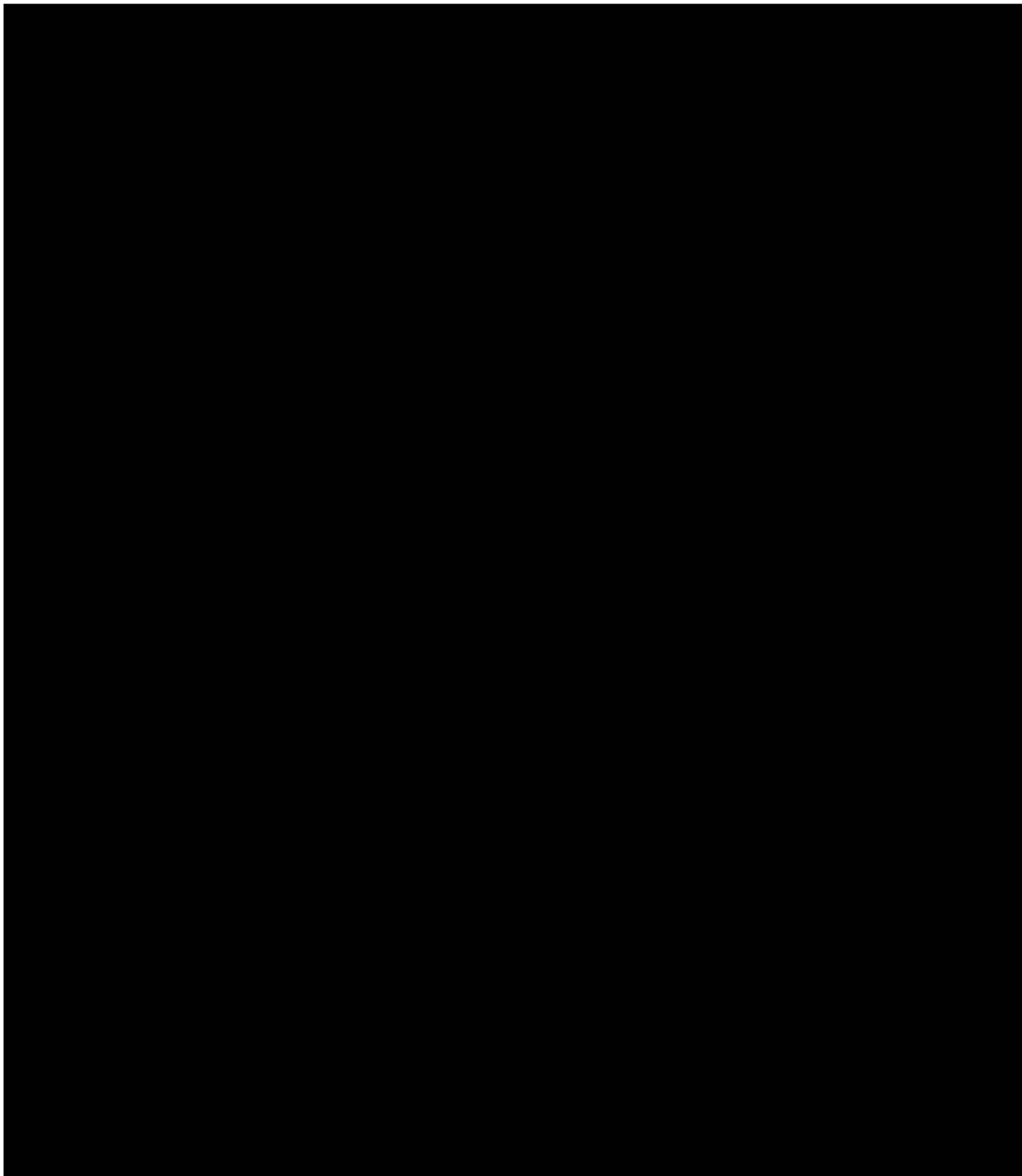


**Minutes of the
Adverse Drug Reactions
Advisory Committee**

296th meeting

3 November 2006



6. Drugs and Associations of Current Interest

6.1 Drugs of Current Interest

6.1.1 DOCI Previews

The Committee discussed general principles involved in the ADRAC DOCI program, including:

- Criteria for selection of drugs for inclusion on the DOCI list;
- Whether non-marketed drugs should remain on this list indefinitely;
- The timing for moving marketed drugs onto the DOCI list - for example, should PBS status be considered, or simply the number of reports received?
- When should drugs be removed from this list, and what are the criteria for removal?

The ADRAC DOCI system is one of the ways by which new drugs are targeted in order to help define their ADR profile early in the post-marketing phase. In general, newly registered new chemical entities expected to receive wide usage become provisional DOCIs and remain provisional for up to 2 years or until they are marketed. Most often, usage will depend on the drug being subsidised under the PBS, but some drugs achieve wide usage even if they are not subsidised. New DOCIs are reviewed after 1-2 years and are removed from the list if usage is low. Marketed drugs that have low usage but are not yet subsidised remain on the list for at least 1 more year if they become subsidised.

DOCIs with high usage remain on the DOCI list for at least 2 years, during which time they are actively monitored and reviewed to assess their adverse events profile. All reports to ADRAC involving DOCIs are provided to the Committee for review and PSUR reports are evaluated. Drugs with high usage are removed from the DOCI list once ADRAC is satisfied that their adverse events profile has been defined adequately *via* the spontaneous reporting system and that no more can be achieved by retaining them on their list, in terms of defining the safety profile.

Members were concerned that the removal of a drug from the DOCI list may be incorrectly perceived as an endorsement of a drug's safety profile. ADRAC agreed that it may be useful to remind practitioners about the principals and definitions involved in the ADRAC DOCI system. This information could be presented in a Bulletin article and on the TGA website.

ADRAC suggested that there should be statements in the Bulletin and on the TGA website to define a DOCI, explain the criteria used to determine which drugs become DOCIs, and explain the criteria used to maintain or delete a drug from the DOCI list.

The Committee was provided a table showing the current DOCI list. The list included provisional DOCIs, which were medicines that had been previously approved for addition to the DOCI list, but had not yet been included because they were not marketed in Australia or because they were marketed but not subsidised under the PBS and their usage remained low.

ADRAC meeting	Generic name	Trade name	Indication	Marketed?	PBS?	ADRAC reports
293; Jun 06	HPV vaccine	Gardasil	vaccine	Jun 06	no	1

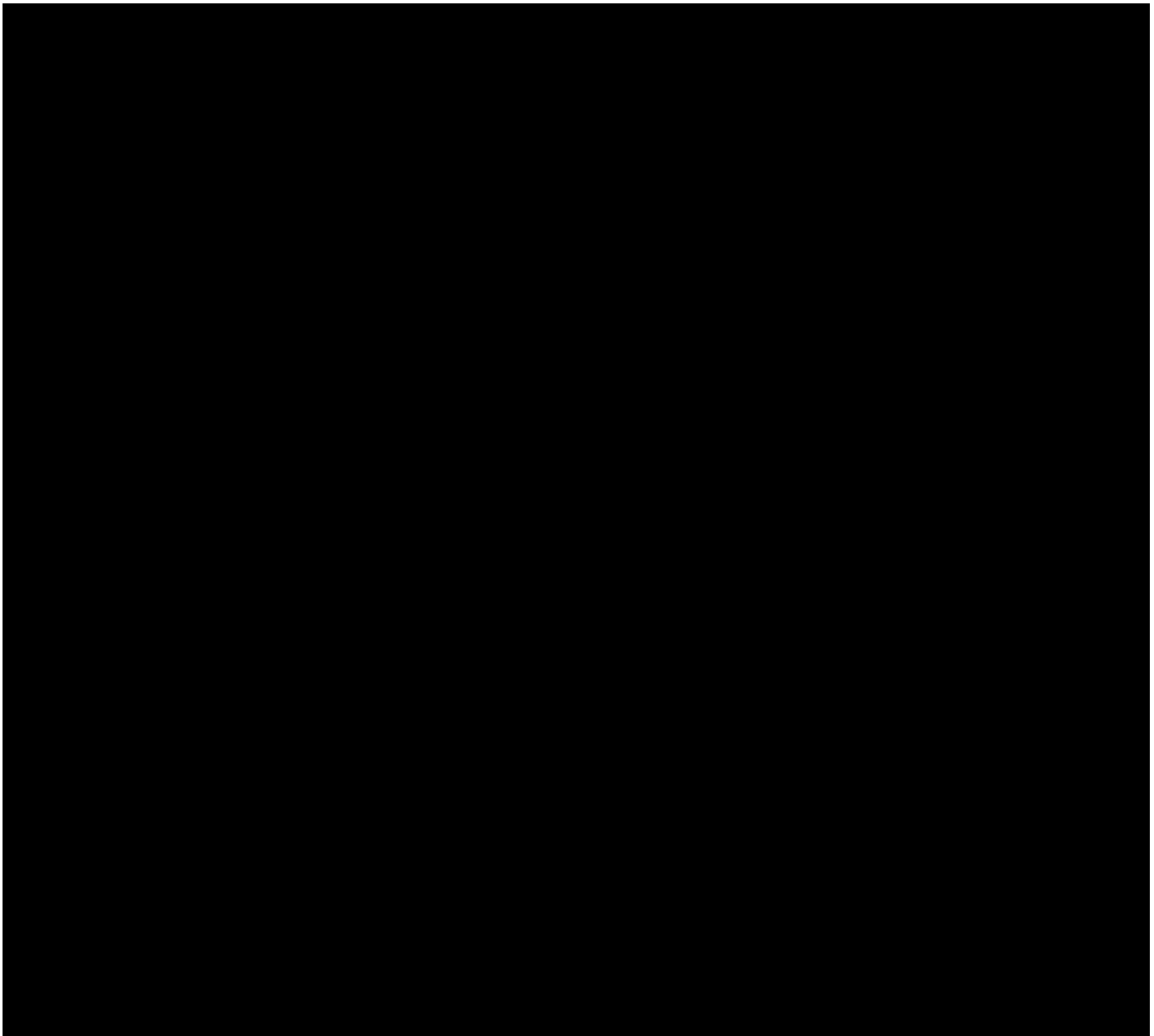
Drugs in **bold** are currently marketed

ADRAC reviewed the status of all drugs currently shown in the table above:

Drug	Comments	Decision
s22		
HPV vaccine	May be used widely if administered to target populations and/or <i>via</i> special schemes	Keep on the list
s22		



10.2 Vaccine reports



Vaccine	Inject. site	Urticaria /rash /pruritus	Irritability malaise	Fever/pyrexia	Dyspnoea/apnoea	Pallor	HHE	Others of potential interest / comments
Papillomavirus							s22	- urticaria



10.2.6 Human papillomavirus vaccine (HPV) and urticaria

Report **s22**

This was the first report to ADRAC of an adverse reaction to Gardasil, which had been approved in June this year for prevention of HPV infection in females aged 19-26 years and males aged 9 to 15 years. The report involved development of urticaria in a 19 year old female, on the same day of vaccination. She was reported to have recovered the following day. ADRAC noted that the vaccine was already in use despite it not being subsidised, and that the reaction was consistent with that observed with other vaccines.

