**Pilot for new process to redact confidential information from PBAC Public Summary Documents**

Since 2005, the Department of Health has published Public Summary Documents to provide context and detail regarding the outcomes of the PBAC. By necessity this publication makes allowance for removal of confidential information provided by a sponsor for the purpose of a PBAC submission. Protection of information that is confidential ensures that sponsors are able to present the best available and most up-to-date data for the PBAC’s consideration without compromising confidentiality.

Before the July 2014 PBAC meeting, removal of such information has been achieved by deletion of reference to confidential information such as proposed prices and details of proposed risk-share arrangements; and by replacing specific values for certain types of information such as incremental cost-effectiveness ratios (ICERs), patient numbers and financial implications with a selection from a standardised set of ranges.

Following the annual meeting between the PBAC and Medicines Australia, it was agreed that the transparency of PBAC Public Summary Documents could be improved. To this end, for the March PBAC 2014 meeting several sponsors agreed to pilot a process whereby reference to unpublished data belonging to the sponsor is redacted (i.e. blacked out) rather than deleted. The resulting Public Summary Documents will appear different to the Public Summary Documents published to date, but will provide greater context and illumination of the PBAC's reasoning process. The use of standardised ranges in place of specific values for certain types of information will remain unchanged.

A hypothetical example is provided below, in which some specific details of results provided to the PBAC:

*The PBAC noted that, based on the results of trial ABC123, patients achieved longer median progression free survival in the treatment arm of 5.0 (95% CI: 3.5, 6.5) months compared with the comparator arm of 4.0 (95% CI: 2.5, 5.5) months (HR = 0.75; 95% CI: 0.6, 0.95, log rank P=0.01). However, patients did not achieve longer median overall survival in the treatment arm of 11.2 (95% CI: 8.3, 16.9) months compared with the comparator arm of 9.8 (95% CI: 7.9, 15.4) months (HR = 0.95; 95% CI: 0.6, 1.35, log rank P=0.4).*

Web-based presentations of PSDs will have confidential information replaced by the word *(REDACTED).*

In this example, redaction of unpublished values allows the publication of the remainder of the paragraph, illustrating the type information taken into account by the PBAC in its deliberations.

The following principles will continue to be applied in deciding to redact information from a Public Summary Document:

* data from clinical trials that are not published or otherwise in the public domain will be redacted;
* the unpublished results of an analysis of a published trial supplied by the applicant will be redacted;
* the unpublished results of an analysis of a published trial performed during the PBAC evaluation process or at the request of the PBAC or one of its subcommittees will be published in full unless it would reveal details of a proposed risk-sharing arrangement;
* where significant portions of a data table require redaction, a descriptive paragraph will follow the table to provide sufficient context to inform the reader without divulging unpublished information;
* specific values for ICERs, patient numbers, numbers of packs supplied and financial implications will be replaced by the following standard ranges used for all Public Summary Documents:
  + ICERs:
    - less than $15,000 per quality-adjusted life-year (QALY)
    - $15,000/QALY - $45,000/QALY
    - $45,000/QALY – $75,000/QALY
    - $75,000/QALY – $105,000/QALY
    - $105,000/QALY – $200,000/QALY
    - more than $200,000/QALY
  + estimated patient numbers and estimated packs supplied:
    - less than 10,000 per year
    - 10,000 – 50,000 per year
    - 50,000 – 100,000 per year
    - 100,000 – 200,000 per year
    - over 200,000 per year
  + estimated financial implications:
    - less than $10 million per year
    - $10 – $20 million per year
    - $20 – $30 million per year
    - $30 – $60 million per year
    - $60 – $100 million per year
    - more than $100 million per year.

At all times, the priority for redaction decisions will be to provide more, not less, detail on PBAC outcomes and reasons and on the evidentiary basis for its decision making.